# NATIONAL CANCER ACT OF 1974

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# HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON

LABOR AND PUBLIC WELFARE

UNITED STATES SENATE

NINETY-THIRD CONGRESS

SECOND SESSION

ON

## S. 2893

TO AMEND THE PUBLIC HEALTH SERVICE ACT TO IMPROVE THE NATIONAL CANCER PROGRAM AND TO AUTHORIZE APPROPRIATIONS FOR SUCH PROGRAM FOR THE NEXT THREE FISCAL YEARS

JANUARY 30, 1974

Printed for the use of the Committee on Labor and Public Welfare

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U.S. Congress. Senate.

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# NATIONAL CANCER ACT OF 1974

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## WEDNESDAY, JANUARY 30, 1974

U.S. Senate,
Subcommittee on Health of the
Committee on Labor and Public Welfare,
*Washington, D.C.*

The subcommittee met, pursuant to notice, at 10:13 a.m., in room 4232, Dirksen Senate Office Building, Hon. Edward M. Kennedy, chairman of the subcommittee, presiding.

Present: Senators Kennedy, Pell, Nelson, Javits, Schweiker, Dominick, Beall, and Taft.

Staff members present: LeRoy G. Goldman, professional staff member, and Jay B. Cutler, minority counsel.

Senator Kennedy. The subcommittee will come to order.

The national cancer program has been in progress for 2 years. Much has been accomplished. But much more remains to be accomplished.

Some major advances have been recorded in 1973. The first artificial gene has been created with potential for life function. A tentative but hopeful approach to immunotherapy for acute leukemia patients has been developed. The first evidence that some form of advanced non-Hodgkin's lymphoma can be controlled for long periods.

Survival of cancer patients overall has almost doubled since the early 1930's. Today, one out of three persons with cancer will be alive 5 years after treatment.

However, as important as these advances have been, an estimated 650,000 new cases will be diagnosed and more than a third of a million Americans will die in 1974.

Unless more progress can be made, cancer will continue to strike one in four of all Americans.

Before the Cancer Act became law, there were only three comprehensive cancer centers in the Nation—two in New York and one in Texas. The act permitted the creation of 15 new centers, of which nine have now been funded, and the other six will be funded by June. But this is not enough.

The Nation needs between 30 and 35 comprehensive centers. No American should be denied cancer treatment simply because of where he may live.

Two of the principal killers are lung cancer and breast cancer. The annual toll for lung cancer is about 75,000 and breast cancer takes the life of one American woman every 15 minutes.

I am, therefore, gratified that the cancer program is making a major effort in both of these areas.

Essentially, I believe this program is working well.

I order a copy of the bill be printed in the record at this point.

The 3-year extension which Senator Javits and I introduced does substantially increase the authorization levels for the program. It also removes the legislative limitation on the number of comprehensive centers which may be funded.

[The text of S. 2893 follows:]

93d CONGRESS
2d Session

# S. 2893

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IN THE SENATE OF THE UNITED STATES

January 24, 1974

Mr. Kennedy (for himself, Mr. Javits, Mr. Cranston, Mr. Eagleton, Mr. Hathaway, Mr. Hughes, Mr. Mondale, Mr. Pell, Mr. Randolph, Mr. Schweiker, Mr. Stafford, and Mr. Williams) introduced the following bill; which was read twice and referred to the Committee on Labor and Public Welfare

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# A BILL

To amend the Public Health Service Act to improve the national cancer program and to authorize appropriations for such program for the next three fiscal years.

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,* That this Act may be cited as the "National Cancer Act Amendments of 1974".

Sec. 2. Section 402 (b) of the Public Health Service Act is amended—

(1) by striking out "in amounts not to exceed $35,000" in paragraph (1) and inserting in lieu thereof

"if the direct costs of such research and training do not exceed $35,000, but only"; and

(2) by striking out "in amounts exceeding $35,000" in paragraph (2) and inserting in lieu thereof "if the direct costs of such research and training exceed $35,000, but only".

Sec. 3. Section 407 (b) (7) of the Public Health Service Act is amended by striking out "where appropriate".

Sec. 4. Section 408 (a) of the Public Health Service Act is amended by striking out "fifteen".

Sec. 5. Section 409 (b) of the Public Health Service Act is amended by striking out "and" before "$40,000,000" and by inserting before the period at the end thereof a comma and the following: "$50,000,000 for the fiscal year ending June 30, 1975, $65,000,000 for the fiscal year ending June 30, 1976, and $85,000,000 for the fiscal year ending June 30, 1977".

Sec. 6. Section 410 of the Public Health Service Act is amended—

(1) by striking out "fifty" in paragraph (1) and inserting in lieu thereof "one hundred";

(2) by striking out "and" at the end of paragraph (7);

(3) by striking out the period at the end of paragraph (8) and inserting in lieu thereof "; and"; and

(4) by adding after paragraph (8) the following new paragraph:

"(9) to award grants for new construction as well as alterations and renovations for improvement of basic research laboratory facilities, including those related to biohazard control, as deemed necessary for the national cancer program."

Sec. 7. Section 410C of the Public Health Service Act is amended by striking out "and" before "$600,000,000" and by inserting before the period at the end thereof a semicolon and the following: "$750,000,000 for the fiscal year ending June 30, 1975; $830,000,000 for the fiscal year ending June 30, 1976; and $985,000,000 for the fiscal year ending June 30, 1977".

Senator **Kennedy.** At the end of my statement, I will insert into the hearing record an appendix which further amplifies the nature of the cancer problem and the progress of the cancer program.

Finally, I want to just make a brief reference to the remarks the President of the United States made when we in the Congress were considering this legislation in 1971. The President stated:

> This, however, will differ from other programs in a very important respect. This program I have asked be the one program within the National Institutes of Health and within the whole health establishment of the United States that is independently budgeted and that is directly responsible to the President of the United States.

Truly, this has been a unique feature of this cancer program. And I am most interested to have a detailed progress report from the witnesses today on how this has worked and whether this mechanism, if it has been successful, might possibly be utilized for other health programs.

[The appendix referred to follows:]

## Appendix to Accompany the Opening Statement of Senator Edward M. Kennedy

"Cancer" is a term applied to more than 100 clinically distinct diseases which kill someone in the United States every 1½ minutes. In 1973, it was estimated that 642,000 Americans will become new cancer cases, 1,310,000 Americans will be cancer patients and 350,000 Americans will die of cancer. The annual cost of cancer is about $18 billion, which cannot measure the incalculable suffering of victims, their friends and families.

Cancer is a widespread biological phenomenon with different incidences, appearances and functioning. It is induced by widely different chemical, physical and biological agents, most of which are unknown. Cancers have many similarities to the host tissues from which they originate. This makes early diagnosis more difficult than with infectious diseases caused by organisms which the body recognizes as foreign to the host tissues. A major effort of the national cancer program is to develop tests which can identify the presence of small numbers of cancer cells with a reliability similar to that of well-known erologic tests for bacterial diseases.

In the early stages of cancer there may be relatively few cancer cells among billions of normal cells. The best chances for curative treatment are at this stage because the balance of forces is in favor of the patient and a skilled therapist. Unfortunately, however, most patients do not seek medical attention until their initial cancer has progressed by abnormal growth and destructive invasiveness to establish new cancerous growths (metastases). If untreated, cancers usually are fatal. However research supported by the National Cancer Institute has developed effective therapies for curing or controlling 10 forms of advanced cancer that were invariably fatal a decade ago.

Cancer causation involves many interrelated factors: heredity, exposure to a variety of agents, singly or in combination and at various doses and routes of administration; host factors that produce different resistences to different agents and different means of handling the many agents (host metabolism, hormonal patterns, immunological responses of the host). Epidemiological data, particularly in occupational settings, have clearly implicated approximately 22 chemical agents in human cancer causation; about a thousand chemicals are now known to induce cancer in animals.

In the early 1900's few cancer patients had any hope of cure. The 5-year survival rate in the late 1930's was about 1 in 5. Ten years later it was 1 in 4 and today the figure is about 1 in 3. This means that roughly 55,000 patients are being saved each year. The immediate goal of cancer control in this country is to save 321,000 lives a year, or half of those who develop cancer. On the basis of 5-year survival, about 224,000 Americans will be saved from cancer this year. About 1,500,000 Americans are alive and free of cancer 5 years after treatment. An additional 1,000,000 cancer patients diagnosed and treated within the last 5 years will live to join these ranks.

Although these improvements in cure rates are impressive and gratifying, the vastly complex nature of cancer requires a coordinated biomedical research effort of unprecedented dimensions. Many methodologies and approaches must be used to solve problems and gain significant new knowledge. Cancer is a chronic disease process, with causation and development extending over several years in most patients. In fact, with several occupational cancers, the period of exposure to the causative agent occurs about a decade prior to the diagnosis. This long time span makes it difficult to evaluate research findings and new methods of prevention, diagnosis, and treatment.

Since its creation in 1937, the National Cancer Institute has been the primary agency through which the Federal Government has sought to marshal biomedical research toward the goal of controlling cancer. The activities of the Institute have been directed toward providing, through research, improved means for the prevention and diagnosis of cancers in man, and the cure and rehabilitation of those cancers that have not been prevented.

The National Cancer Act of 1971 rested on the conviction that medical and scientific understanding of cancer had reached a level where sustained pursuit of new scientific leads could advance national capacities to prevent, diagnose, and treat cancer. The act stipulated that an intensified and coordinated national program would be needed to quicken the pace for developing the means to bring cancer under control.

The National Cancer Act gives the National Cancer Institute the responsibility for organizing this complex undertaking and for channeling the resources needed for this program. The act specifically directs the director of the Institute to "plan and develop an expanded, intensified, and coordinated cancer research program encompassing the programs of the National Cancer Institute, related programs of the research institutes, and other Federal and non-Federal programs." This mandate includes support for cancer research in industry and in other countries outside the United States.

To speed the translation of research results into widespread applications, the act directs the establishment of a cancer control program to demonstrate to both the medical community and general public the applications of the latest advances in cancer prevention and control.

The act further directed the Institute to provide supporting resources for the national cancer program. These include:

Collection, analysis and dissemination of all data useful in the prevention, diagnosis and treatment of cancer, including establishment of an international cancer research data bank.

Continuing support of appropriate manpower training programs in fundamental sciences and clinical disciplines.

Support of the large-scale production and distribution of specialized biological materials and other chemicals and drugs for research.

An overall strategy for the national cancer program has been developed, based on a consensus among Federal and non-Federal clinicians and laboratory scientists about the direction, content and pace of the research program. The strategy and plan for the national program will be revised regularly as new information and concepts flow from the laboratory and clinic. The overall strategy involves the systematic sharing of cancer information by public and private agencies throughout this country and abroad. It requires continued assessment of resource needs and logistical planning to meet those needs. In some cases, it necessitates the redeployment of existing facilities, the rapid evolution of new kinds and combinations of research support, the reassignment of science management responsibilities, and the development of new mechanisms of technological transfer and information retrieval and application.

The national cancer program plan includes a strategic plan and an operational plan. The strategic plan, developed with a broad spectrum of advice from the scientific and medical communities, presents the major national goal, objectives, program strategy, implementation strategy, and estimated resources necessary to achieve the objectives. The operational plan, which is nearing completion, will include more detailed information concerning plans for specific research programs to implement the strategic plan.

A preliminary outline of the national cancer program plan and the research strategy was developed by the National Cancer Institute with the advice of the National Advisory Cancer Council. Then, in a unique event in the history of biology and medicine in this country, 250 laboratory and clinical scientists met in a series of 40 planning sessions between October 1971 and March 1972 to develop a scientific and operational foundation for the national cancer program. The resulting strategic plan was reviewed by the President's Cancer Panel, the National Cancer Advisory Board, the director and staff of the National Institutes of Health, National Cancer Institute staff, the Association of American Cancer Institutes, the American Association for Cancer Research and the Institute of Medicine of the National Academy of Sciences.

The goal of the national cancer program is to develop means to significantly reduce the incidence of cancer in man and the suffering and death from cancer. The general strategy of the program is to provide for a balanced effort covering the entire spectrum of basic applied and developmental research. The strategy will be implemented through laboratory, field and clinical programs that are judged most likely to produce the information and technology that can be transferred rapidly to medical practice. The program will be "balanced" in the sense that all promising options will be pursued, taking into account the current state of research knowledge, the probability of success of the option, and the impact of the successful completion of the option.

The national cancer program has a mandate that goes beyond the traditional NIH research mission. Simply stated, the program must build effective bridges from laboratory and clinical research to those who can benefit from the results of research—to physicians, their cancer patients, and all at risk to cancer.

## CENTERS

The most visible manifestation of bridge building during the past year has been the establishment of a national network of cancer centers demonstrating optimum cancer care at locations selected to provide maximum public and professional access.

In 1971, when the National Cancer Act granted NCI authority to establish clinical cancer research and demonstration centers, there were three preexisting comprehensive cancer centers: The M. D. Anderson Hospital and Tumor Institute, Houston; Memorial Sloan-Kettering Cancer Center, New York; and Roswell Park Memorial Institute, Buffalo.

Some 20.6 million people were within 60 miles of these three centers and 33.7 million people were within 120 miles.

Within the past year, nine additional medical institutions have established comprehensive cancer centers with assistance from the National Cancer Institute. These institutions are:

University of Alabama School of Medicine, Birmingham.
Children's Cancer Research Foundation, Boston.
Duke University Medical Center, Durham, N. C.
Fred Hutchinson Cancer Research Center affiliated with the University of Washington, Seattle.
The Johns Hopkins Medical Institutions, Baltimore.
University of Miami School of Medicine, Miami.
Mayo Foundation, Rochester, Minnesota.
University of Southern California (with the Los Angeles County Department of Hospitals), Los Angeles.
University of Wisconsin Medical Center, Madison.

As a result, today, 53 million Americans are within 60 miles of a comprehensive cancer center and 92 million are within 120 miles.

The distances 60 miles and 120 miles are not arbitrary. Studies show that 60 miles is generally the greatest distance a patient can reasonably drive for daily therapy, and 120 miles is the greatest distance a patient might be expected to travel for consultation without requiring an overnight stay.

By July 1974, at least six additional comprehensive centers will be underway. At that time, well over one-half the population should be close enough for a patient to visit a comprehensive cancer center for a consultation and return home the same day by surface transportation. The country will need 30 to 35 comprehensive cancer centers to serve adequately the entire U.S. population.

Now, I want to describe the particular aspects of my bill. First of all, it is a 3-year extension of the act through June 30, 1977. The bill proposes substantial increases in the two sets of authorization levels for the program. For the basic research and training program, the bill authorizes $750 million, $830 million, and $985 million for the fiscal years 1975, 1976, and 1977, respectively. For the prevention and control program, the bill authorizes $50 million, $65 million, and $85 million for those same fiscal years. The bill also removes the limitation in the act which prohibits the creation of not more than 15 comprehensive cancer centers. I believe the Nation requires 30 to 35 such centers in order to bring high quality comprehensive cancer care within the reach of everyone. I can see no reason why any family should be denied the best possible cancer diagnosis and treatment simply because of where they live. Finally, the bill makes a number of minor though important technical amendments to the Cancer Act.

---

Senator KENNEDY. This morning, the subcommittee is privileged to receive the testimony of a host of distinguished persons. I certainly hope that, based upon today's testimony, the committee can promptly report legislation to the Senate. Clearly, there must be no hiatus in the continued operation of the national cancer program.

Let me say at the outset that we are delighted to have the distinguished Secretary of HEW here to present the administration's program. He has appeared before this committee on many different occasions, and we want to welcome him back with his associates.

We want to mention, Mr. Secretary, that we applaud the efforts of the administration. The funding of this program has not quite reached the levels that we expected, but I think that the administration deserves credit for giving a sense of priority to this program.

I am also mindful that one of the features that troubled the administration was the prevention and control program, and I think the administration has demonstrated good faith with the Congress in developing active programs in this area.

I think that the work that they have done in combining the Federal Government's participation with that of private organizations, such as the American Cancer Society, is an excellent example of the type of cooperation that can exist between the Federal Government and private associations, and I think you are to be commended for that.

We are delighted that Dr. Rauscher is here, as well, and we want to commend him for the leadership that he has provided.

We will be interested in any comments he would like to make, particularly in the manpower area;

We have just had a chance to review your testimony. There are a few points which we would like to develop with you, and we look forward to your responses.

I want to recognize the Senator from Colorado, Senator Dominick, who has been so interested in the development of this program and the effect of our legislation in this area. He has been enormously interested in this subject matter as he has in so many other health areas. We have benefited tremendously from his participation in all our deliberations.

I will ask him to make whatever comments he would like.

Senator Dominick. I am just delighted we are holding these hearings. I look forward to listening to the Secretary's testimony.

We in Colorado already have an application in for a National Center for Cancer, and I think we are in a very favorable position as opposed to most of them who are apparently looking for 75 percent Federal support. We have about 65 percent of local already, which leaves us, I think, at a very favorable spot.

We also have an integrated program with our medical school and all the other hospitals and institutions in the area, cooperating in one management under a very skilled cancer expert.

I am looking forward with anticipation to the selection of this as a National Cancer Center.

I think it is worthwhile trying to determine as we go along how many of these are going to be fruitful in terms of having enough expertise to go forward with research on the causes and solutions for the problems which we have. Certainly, this is not any kind of an easy disease. There is no one solution because there are so many varieties of cancer.

As I think I said to the Chairman before, it was my anticipation that by keeping it within the interrelated disciplines that we have in the medical field, that some fellow with a research grant out of some place we never heard of would suddenly come up with a real advance.

At about that time, they discovered the viral materials in Canada out of injections into a goat.

This proved, I think, the necessity for interrelationship between all the various types of medical research which is going on.

I look forward with anticipation to hearing from the Secretary, who has a firm grip on this particular piece of research which is so vital to the health of the American citizens.

Senator Kennedy. Thank you very much, Senator Dominick.

We have been joined by the ranking minority member of the Health Subcommittee, Senator Schweiker. He is a co-sponsor of the legislation, and he has been enormously interested in its development. We want to welcome him this morning. And we are interested in any comments he would like to make at this time.

Senator Schweiker. Thank you very much, Mr. Chairman.

I just want to say I am delighted we have the opportunity to hold hearings on this very important topic. I think they will be constructive.

I know the administration has a strong commitment to the cancer effort.

I am looking forward to hearing the Secretary's statement as well as this committee's consideration of our national interest in this area, which I regard as vital. I look forward for the hearings to unfold.

Senator Kennedy. Senator Javits has a statement to include.

Senator Javits. Thank you, Mr. Chairman. The bill I introduced with Senator Kennedy will continue the advances made against the dread killer disease, cancer. This national commitment to the conquest of cancer grows out of legislation Senator Kennedy and I introduced in 1971, which laid the groundwork for the enactment into law of the National Cancer Act of 1971, Public Law 92-218.

This measure we introduced January 24, 1974, will assure that cancer research continues within the NIH and maintains its separate budget—at an increased level of $2,765 million over the next 3 years—to insure the necessary top priority to fulfill our national commitment to launch a meaningful attack on cancer.

I believe that we must continue—at an increased rate—an intensive and sustained program of cancer research on all fronts. We must also seize hold of our scientific insights and advances and exploit them to their fullest potential. We can most effectively achieve this desired goal by moving forward with the establishment of cancer research and demonstration centers of excellence.

Unfortunately, under existing law these centers for clinical research, training, and demonstration of advanced diagnostic and treatment methods relating to cancer are limited to 15. Therefore, the bill I introduced with Senator Kennedy would eliminate this limitation—action which would be in accordance with the recommendation of the National Cancer Advisory Board and the President's Cancer Panel.

Other proposed changes—including the increased funding authorization levels—required by our "National Cancer Act Amendments of 1973" also represent the views of the National Cancer Advisory Board, concurred in by the President's Cancer Panel, and are a matter of public record. I would urge the administration to adopt them as their official recommendation.

I would urge the President to continue his commitment to the conquest of cancer, evidenced by his signing into law the National Cancer Act of 1971 and by his 1971 state of the Union message where he said: "The same kind of concentrated effort that split the atom and took man to the moon should be turned toward conquering this dread disease."

Cancer kills someone in the United States every 1½ minutes. In 1974, 1,310,000 Americans will be cancer patients and 350,000 Americans will die of cancer. The annual cost of cancer to the economy is about $18 billion, which cannot measure the incalculable suffering of victims, their friends and families.

Although the improvements in cancer cure rates are impressive and gratifying—in the early 1900's few cancer patients had any hope of cure, the 5-year survival rate today is about 1 in 3 which means that roughly 55,000 patients are now being saved each year—the vastly complex nature of cancer requires a coordinated biomedical research effort of unprecedented dimensions. Many methodologies and approaches must be used to solve problems and gain significant new knowledge.

We must speed the translation of research results into widespread applications, and demonstrate to both the medical community and general public the applications of the latest advances in cancer prevention and control.

Senator KENNEDY. Thank you very much.

Mr. Weinberger.

## STATEMENT OF HON. CASPAR W. WEINBERGER, SECRETARY OF HEALTH, EDUCATION, AND WELFARE; ACCOMPANIED BY STEPHEN KURZMAN, ASSISTANT SECRETARY FOR LEGISLATION, DHEW; CHARLES C. EDWARDS, M.D., ASSISTANT SECRETARY FOR HEALTH, DHEW; ROBERT S. STONE, M.D., DIRECTOR, NATIONAL INSTITUTES OF HEALTH, DHEW; AND FRANK J. RAUSCHER, PH. D., DIRECTOR, NATIONAL CANCER INSTITUTE, NATIONAL INSTITUTES OF HEALTH, DHEW

Mr. Weinberger. Thank you, Mr. Chairman and members of the Committee.

We certainly appreciate your generous comments, Mr. Chairman, and we are, of course, pleased to be here to testify in support of the extension of the programs authorized by the National Cancer Act of 1971, the authorizations for which expire on June 30 of this year.

We are glad that the hearings are being held this early in the year so that there will be no interregnum in the program.

I would like to make a few introductory remarks. Before I do that, I received a letter from the President late last night, and I would like to put that in the record and read it if I might.

It is from the President, addressed to me.

[The President's letter follows:]

THE WHITE HOUSE
WASHINGTON

January 29, 1974

Dear Cap:

It has come to my attention that you will appear tomorrow at Senate hearings called to consider the extension of the National Cancer Act of 1971 when it expires on June 30. I want you to know that I strongly support an extension of this Act with whatever improvements might be made in consultation between the Executive Branch and the Congress.

I continue to have strong and continuing interest in this program. I remain just as committed to the attack on cancer as I was when I signed the original legislation on December 23, 1971. Our joint efforts with the Congress in this area have provided an excellent example of the ability of the Executive and Legislative Branches to work together in dealing with a major problem.

I have followed progress on the attack on cancer carefully. In addition, I have met with Benno Schmidt and other members of the President's Cancer Panel and have reviewed their report and the report of the National Cancer Advisory Board with great interest. It is my feeling that considerable progress has been made in the attack on cancer in recent years and that there is much hope for additional knowledge that can be developed in the future.

That is why I plan to ask for an additional $100 million above last year's request of $500 million for the expanded attack on cancer in the budget that I will be submitting to the Congress next Monday. I realize that this will result in spending over $415 million more for this effort next fiscal year than was available the year I took office, but I think the dual goals of an expanded research effort to find the causes of cancer along with more intensive demonstration and education programs to help prevent and control cancer warrant this support.

I hope you will share my strong interest in this program with the members of the Committee and express my appreciation for their past efforts in enacting the National Cancer Act of 1971.

Sincerely,

Richard Nixon

Honorable Caspar Weinberger
Secretary of Health, Education,
and Welfare
Washington, D.C.

Senator **Kennedy**. I just want to say, Mr. Secretary, that that is a splendid letter, and I think those who are concerned about this program will be very much heartened by the President's strong statement of support for this cause. I do not think that any of us doubted his interest in cancer research, education, and control but I think it is very reassuring to hear his affirmation of support.

I commend the President for making it.

Mr. **Weinberger**. Thank you, Mr. Chairman.

I think it is indicative of the President's very strong support that he is willing to take this rather unusual step of revealing the specific budget request this far in advance of submission of the budget.

He was particularly anxious that this be before you today, and so I am delighted to have the chance to present it.

Senator **Kennedy**. Fine.

Mr. **Weinberger**. The administration and Congress have both been deeply committed to the expanded cancer research program which was augmented in December 1971, when President Nixon signed the National Cancer Act.

Our joint efforts in these areas have indeed provided an excellent example of the ability of the executive and legislative branches to work together in dealing with a major problem.

Cancer, in its more than 100 forms, still constitutes a devastating health problem for the citizens of this country and, indeed, for mankind everywhere. Cancer continues to be the second leading cause of death in this country and the incidence of new cases continues to increase.

Yet the outlook is improving at a steadily accelerating pace. One out of every three persons who now have cancer can expect to be alive 5 years after treatment.

There are 1½ million Americans who have had cancer but are now well. An additional 1 million cancer patients diagnosed and treated in the last 5 years are expected to live to join these ranks.

Much of this progress and the hope for the future is a result of the increased emphasis of the cancer research effort as administered by the National Cancer Institute and the NIH, in cooperation with many private and public groups.

This effort has a dual mission. The first is to speed the development of new knowledge by an intensive and coordinated research effort involving the broad scope of medical, biological, chemical, and physical sciences. The second is to demonstrate the most effective methods for the prevention and control of cancer through dissemination and educational activities.

This demonstration of research results applies the best of our present knowledge and will provide for the rapid application of new information as the national cancer research effort continues to gather momentum.

This dual approach has resulted in much progress, which has brought us closer to the answers we need. This progress has been the product of cooperative public and private efforts in the areas of cancer cause and prevention, detection and diagnosis, treatment, and rehabilitation.

We do not expect that there will ever be a single cure for the many forms of cancer. Instead, scientists and physicians are exploring all promising avenues of research that may lead to identifying the causes of cancer, preventing cancer whenever possible, diagnosing cancer earlier and more accurately, and treating it more effectively.

The host of individual advances all work toward the ultimate goal of preventing the occurrence of cancer, curing cancer when it does occur, and restoring former cancer patients to full productive lives.

To implement these programs more effectively, the National Cancer Institute has recently undergone a major reorganization to assist the Director in carrying out his new and additional responsibilities as Director of the National Cancer Institute.

Mr. Chairman, I would like to submit for the record a chart depicting this organization.

[The chart referred to appears as a fold-in following the last page of this hearing record.]

Mr. Weinberger. I would also like to note, as the President has, the significant budgetary increases that have been provided.

In 1971, the National Cancer Institute (NCI) appropriation level was approximately $233 million. Today, the budget level has more than doubled. The 1974 appropriation would provide up to $551 million. The President has requested an additional $100 million above last year's request, as you have just heard, which will raise the requested level in the 1975 budget to $600 million for the cancer program.

National Cancer Institute operations are only one of the avenues of approach. The understanding of the abnormal growth and spread of cancer is inextricably linked to the biology of normal cells.

The National Cancer Act recognized that "the present state of our understanding of cancer is a consequence of broad advances across the full scope of the biomedical sciences." This ranges from the molecular biology of genetic control to the biochemistry of cell membranes, metabolism, and immunology.

The National Institute of General Medical Sciences, the National Institute of Allergy and Infectious Diseases, the National Institute of Arthritis, Metabolism, and Digestive Diseases, along with the National Cancer Institute and the other Institutes, are responsible for exploring these fundamental life processes through support of basic research. These processes are still far from being fully understood.

The administration's support of basic research was almost $400 million in 1973. That was, incidentally, an increase of about $90 million over 1969.

Interaction between scientists of the various institutes in the area of basic biomedical research and with the scientific community at large is intense. The clues to advances in cancer may well come from research done and supported by other institutes just as clues to advances in their areas of responsibility may come from research done or supported by the National Cancer Institute. That is why it is so important to maintain a close working relationship between National Cancer Institute and the other institutes.

Increased participation in cancer research by scientists in industry and in educational and other nonprofit institutions also has been achieved as called for by the act.

In 1971, National Cancer Institute had 1,096 active grants and 252 contracts with educational and other nonprofit institutions, and there were 139 contracts with profitmaking firms.

In 1974, the National Cancer Institute will have an estimated 1,747 grants, 753 continuing contracts and 292 new contracts.

The international scientific community has also been brought into the cancer research effort, as called for by the act.

Research in 19 foreign countries is being supported by National Cancer Institute.

Especially noteworthy is the broad cooperative cancer effort that has taken root through the Joint U.S.–U.S.S.R. Health Agreement of 1972. One result of that agreement is the Telex-line, which I opened by agreement with the Soviet Minister of Health when I was in Moscow last year. That has enabled cancer scientists in the United States and the U.S.S.R. to communicate with each other daily since mid-October.

This system is used to exchange information on such things as the use of drugs, the exchange of scientists, and the shipment of materials.

I would like to describe briefly some of the accomplishments against cancer which have been made.

1. Research results to date.

First, in the research effort there is a new emphasis on developing treatment methods that effectively use combinations of surgery, radiation, and drug therapy.

As a result, half of those children with acute lymphocytic leukemia, a cancer of the blood, now are alive 5 years after diagnosis, when treated aggressively with radiation and a combination of anticancer drugs. Twenty years ago, this disease struck down most of its victims within a few months.

Radiotherapy for the early stages of Hodgkin's disease, another cancer of the circulatory system, produces 5-year survival rates of more than 90 percent. This is compared to a 68 percent survival rate for early Hodgkin's disease 5 years ago. A four-drug combination treatment for advanced Hodgkin's gives a 65 percent survival rate after 5 years, a vast improvement over the survival rate of less than 10 percent 5 years ago.

There are indications that breast cancer may yield eventually to a combination of drugs, surgery, and radiation. Overall 5-year survival rates for this disease, which kills more women than any other form of cancer, have remained near 60 percent for the past two decades. Scientists now have found significant decreases in tumor size when advanced breast cancer patients are treated with any one of six drugs.

Although these observations do not show any lengthening of these patients' lives, they are essential first steps toward improved treatment for breast cancer in the future.

Adriamycin, another experimental drug, has been found to have activity against a broader range of cancers than any other known drug. This includes breast cancer and lung cancer, the leading cancer killer among American men, and now the third greatest cause of cancer deaths among women as well.

Research now centers on developing less toxic forms of the promising drug.

Second, progress has been made in the early detection of cancer.

For example, x-ray examination used in combination with physical examination in studies of mass screening for breast cancer has resulted in a one-third reduction of the death rate from that disease over a 5-year period for the individuals in that study.

Another report in 1973 showed the value of periodic examinations for colon-rectal cancer, the second greatest cause of cancer deaths among both men and women.

A study was conducted of 18,000 persons over age 50 who had over the past 25 years received periodic examinations of the lower colon, and removal of polyps or other pre-cancerous conditions. The rate of colon cancer among these individuals was only 15 percent of that expected if they had not been examined regularly.

Scientists are using immunologic techniques to detect cancer-related chemicals, or "markers," in the blood or urine of persons with cancer. One such marker, called carcinoembryonic antigen (CEA), may be useful in combination with other tests for cancers of the digestive system, particularly colon cancer.

Third, progress in understanding the causes of cancer may lead to its prevention as well.

In this regard, the National Cancer Institute has been able to step up its program to identify cancer-causing chemicals in the environment. Approximately 445 chemicals are now being tested in 2-year and 3-year studies with animals. The tests are underway at 20 laboratories, including the Frederick Cancer Research Center, converted by Presidential mandate from a biological warfare center, at Fort Detrick, Md.

No virus has yet been found to cause human cancer, but scientists are accumulating evidence for some type of association of several viruses with breast cancer, leukemia, cancer of the cervix, and other forms of cancer.

A battery of highly sensitive biochemical and immunologic tests have been developed for this research. These tests have been used to show that at least two suspected human cancer viruses are actually of animal origin, important information which allows National Cancer Institute to direct its resources elsewhere.

Finally, several totally new approaches for cancer control and prevention may ultimately emerge from fundamental research into the life processes of cells.

These include an artificial and potentially functioning gene which has been synthesized for the first time. Years of further research may lie ahead, but scientists hope artificial genes can be used to learn how cancer starts, and how it can be stopped.

Genes direct the synthesis of enzymes that cells need to function. There is new evidence for several enzymes that may appear only in cancer cells. If these enzymes are essential for cancer, blocking the enzymes may kill cancer cells while leaving normal cells unharmed.

Turning to its second thrust, I am pleased to report that the National Cancer Institute, working with cancer centers around the country, has posted an excellent record in delivering research results to the people. We are doing what can be done, now, for the cancer patient and those at risk to cancer.

Nine major medical institutions across the country have established comprehensive cancer centers. The remaining six centers authorized by the National Cancer Act will join these ranks by July 1.

In addition, three pre-existing centers of comparable scope have been strengthened. These centers engage in the full range of basic and clinical cancer research and teaching. They demonstrate and assist other institutions in their surrounding areas to provide the best possible programs of cancer prevention, detection, diagnosis, treatment, and rehabilitation.

Cancer control activities, also called for by the National Cancer Act, have been firmly established. This new program is speeding the application of research advances through relatively short-term projects conducted in and out of major centers such as:

In cooperation with the American Cancer Society, 20 breast cancer detection projects have been established throughout the country. More than 100,000 women will be screened annually to find breast cancers in the earliest possible state—when this leading cause of cancer death among American women is most curable.

A network of more than 100 community hospitals is being established to demonstrate effective new treatments for acute lymphocytic leukemia, Hodgkin's disease, and non-Hodgkin's lymphonas.

Collaboration with the HEW National Clearinghouse for Smoking and Health is aimed at reducing the number of cancers caused by smoking.

Several centers and hospitals are developing model cancer rehabilitation programs that can be replicated in community hospitals as well as in the large centers for cancer care.

The National Cancer Institute also conducts and supports clinical research involving all 36 major forms of cancer. More than 20,000 patients, 1,600 physicians, and 320 cancer centers and other hospitals throughout the country are participating in these programs. This is the frontline where new approaches are being tested for treating cancer, and where results of research being done elsewhere is brought out as soon as possible.

The bill before you would extend the appropriation authorization in the National Cancer Act of 1971 for 3 years, raising the authorization levels to a total of $750 million in 1975, $830 million in 1976, and $985 million in 1977.

The bill would also make certain other changes in the act. It would remove the statutory limitation of 15 new cancer research and demonstration centers. It would raise the authorization for scientific or expert consultants from 50 to 100. It could also expand the construction authority of the act to include construction of nonclinical basic research facilities.

Proposals for change: The administration and this committee are, I believe, in full accord in our commitment to maintain the momentum of the cancer research effort. It has the highest health priority in our administration.

We do disagree on certain of the specifics of the approach to be taken. These differences arise from our need to consider it against the background of the total resources we have for other health research efforts and for other health programs as well.

We agree, as I have stated before, that the forward thrust must be maintained and enhanced. We would, however, ask that the following changes be incorporated into S. 2893.

First, we prefer that specific authorization levels for the cancer control program and for the remainder of the program be deleted in favor of a single authorization, "such sums as may be necessary."

We feel strongly that this language adds additional necessary flexibility to our efforts to manage the resources available for health programs. As noted earlier, the funding requested for fiscal year-1975 represents an increase over that appropriated in fiscal year-1974.

Senator KENNEDY. Mr. Secretary, what has been the reason for the change in the administration's position?

You did not oppose the dollar limitation in the previous legislation.

Mr. WEINBERGER. I do not recall what the position was when the legislation was up 3 years ago. I was not here.

But I do know that recently in a wide number of fields, even beyond health, we have taken the position that it is more flexible and that it is always an improvement simply to authorize "the amount that may be necessary."

The problem is, of course, that authorizations, as in this bill, when they are in specific amounts, run 3 years ahead of the time when the actual appropriation comes along.

We feel that there is no real way of knowing what amount can be appropriated. It may well be that more is necessary than the authorization.

The other problem in other fields has been that very large authorizations have created a lot of completely unrealizable expectations.

The authorization, therefore, has a kind of unrealistic tone that may bear no relationship to what the Appropriations Committee actually appropriates.

Senator KENNEDY. That has not been true with this particular program.

Mr. WEINBERGER. No; it has not been true about this particular program. But it may well be that more would be required in the authorization legislation in 2 years. It may well be that that authorization level would be about what would be appropriated.

It may well be that something below that would be appropriated.

The authorization of a specific amount two, three, four, five years ahead, we feel, is not only unrealistic but adds nothing to the development or execution of the program. We feel it is much better for the authorizing committee simply to say "such sums as may be necessary," and then that would permit the actual amount at that time to be fixed by the Appropriations Committees.

Senator KENNEDY. Then you might as well abolish the authorizing committees. If your account is correct, then we are wasting our time in holding legislative hearings. We should merely allow the Appropriations Committees to do all our work for us.

Mr. WEINBERGER. No; I do not think that follows at all.

I think the authorizing committees have a real function to consider the necessities, dimensions, and details of the programs.

I do think that as long as the Congress maintains the difference between authorization and appropriation and has different committees approaching that same basic dollar amount problem, that it is a better plan for the authorizing committees not to try to fix with any degree of definiteness even the outside limits of the sums this far ahead.

I am told that our request in 1971 was for the same language, "such sums as may be necessary."

Senator KENNEDY. What information will the Appropriations Committees have that we will not in order to set priorities?

Mr. WEINBERGER. For one thing, they will have far more up-to-date information. They will be considering the appropriation in the context of the year in which the money will be asked for and spent.

We are here this morning talking about programs 3 years distant from now, actually a little bit more than that.

Senator KENNEDY. What we are concerned with is overall goals. That is the way the legislative system has worked; it permits the appropriating committees to appropriate those funds within the context of the goals of the authorizing Committee.

Mr. WEINBERGER. My point is, Mr. Chairman, those goals cannot be realistically set in dollar terms at this time.

For one thing, we do not know what the inflation factor will be. We have no way of knowing whether $750 million or $850 million is the proper outside limit for a cancer program 2 years down the road.

We do have authorization committees that are supposed to address those more or less specific subjects at that time.

Our suggestion simply is that you allow the authorization of enough money as may be necessary and then let the specific amounts be set. I suggest that it could be an unwelcome limitation, or it could be an unrealistic amount, when we try to fix it at this point this far ahead of the actual year in which it is to be used.

Senator DOMINICK. Will the chairman yield to me?

Senator KENNEDY. Let me make a final point, and then I will yield.

We will put in the record the authorizing figures for 1972, 1973, and 1974. Let me assure you that should the administration feel it needs more funding in terms of authorization or appropriation I hope you will feel completely free to notify the members of this committee. And I guarantee you that we will get expeditious action.

[The information referred to follows:]

## NATIONAL CANCER ACT -- FUNDING HISTORY

(in millions)

| | 1972 | | 1973 | | 1974 | |
|---|---|---|---|---|---|---|
| | Authorization | Appropriation | Authorization | Appririation | Auth | Approp |
| Basic Program | 20 | 0 | 30 | 4 | 40 | 34 |
| Prevention and Control | 400 | 378.8 | 500 | 492* | 600 | 551.2 |

* 60.0 of this total was impounded by the Administration

Mr. Weinberger. We certainly would, Mr. Chairman.

It is our concern that there are so many other members of both Houses involved that the delays involved in securing the increased amounts might be unreasonably protracted.

Senator Kennedy. We are glad you are thinking in terms of the upper limits, rather than the lower limits.

Senator Dominick.

Senator Dominick. I have to say that this position of the administration or of your position—I do not know whether it is all administration or not—violates my fundamental principle that I have here in Congress.

I do not know whether the amounts which Senator Kennedy has in this bill are right or wrong. We can find out some more of this as testimony is given.

If you put in "such sums as may be necessary," what you are doing is to turn over the whole authorization process to the Appropriations Committee. You are, in fact, doing back-door spending.

We would have no idea whatsoever of the total amount of authorization in order to put it into a budgetary procedure. That has been part of my problem with "such sums as may be necessary."

I might say, Mr. Secretary, you are not the first secretary who has asked for this. It happened under President Kennedy and it happened under President Johnson, and I have always objected to it.

I would hate to see us go that route, I really would.

Mr. Weinberger. It would not appear on the basis of these two statements, Senator, that there is much danger of that.

Senator Dominick. All right.

Senator Javits. Would you yield to me a moment?

Mr. Chairman, I would like to know how the Secretary squares his views on "such sums" with the views of the President himself.

He says, in the endorsing letter, that he is going to ask for $500 million.

Now, do you not think, Mr. Secretary, that we ought to advise the Senate from the expertise of the authorizing committee, as we know most about the substantive aspects of it, whether we think that sum is right or wrong, and in order to do that, we have to express a figure of authorization?

Otherwise, we leave absolutely, as Senator Kennedy said, to the Appropriations Committee our function, which is to exercise expertise respecting this particular matter.

I can understand it if you tried to make a case for "such sums after the first year."

We have done that on occasion, although I have always sustained Senator Dominick's position in that, and I would again, but, nonetheless, I can understand it.

But I really do not see how you can ask us to deny to the President the courtesy, the responsibility of our telling the Senate that we do or do not agree with the figure that he himself said he is going to ask for.

Mr. Weinberger. Senator, there are two points. First of all, the President's letter asks for $600 million, not $500 million.

Senator Javits. Well, whatever the figure is.

Mr. WEINBERGER. And the second point, you would not be denying the President the courtesy of advising the Appropriations Committees of the amount involved if you put into your report that you felt that his request was entirely appropriate.

As far as stating the appropriation limit for this year is concerned, and specifying "such sums as may be necessary" for the other years, I think that would be an acceptable compromise which we could work with you to try to secure.

Senator JAVITS. Thank you, Mr. Chairman.

Mr. WEINBERGER. Continuing with the statement, Mr. Chairman, we do not believe that additional categorical cancer centers beyond the 18 now established (15 new, three strengthened) should be constructed at this time.

We feel that the existing three centers, in addition to the 15 centers authorized in the act constitute an adequate and effective demonstration effort.

All 18 will be on line this year. The National Cancer Institute estimates that 18 centers will provide outpatient care within a 60-mile range to approximately 45 percent of the U.S. population and inpatient care within a 120-mile range to over 80 percent of the population.

With this amount of population covered, these centers can effectively carry out an essential mission of demonstrating the best methods of cancer treatment. To support any more of these centers would move the Federal Government dangerously close to a complete cancer-based treatment responsibility. This role would not only be an undesirable and unnecessary one for the Federal Government, but would create serious equity problems by providing special Federal subsidies on a categorical basis.

We feel that the Federal Government's resources will be used far more appropriately and effectively against this serious health problem by concentration on research and demonstration of effective modes of care, and then provide for the delivery of the research results in the manner in which we are now doing.

The last two proposals in S. 2893 (to delete the words "where appropriate" from section 407(b)(7) and to increase the number of experts and consultants in section 410(1) from 50 to 100) are not needed and would not enhance the operation of the National Cancer Institute. These proposals were suggested by an ad hoc committee appointed by the National Cancer Advisory Board and have not been identified by the National Cancer Institute as creating administrative problems.

In summary, Mr. Chairman, we are pleased with the progress made by the expanded cancer research effort. We firmly support your efforts to continue the program and, with the changes which we have suggested, would be glad to support S. 2893.

I am accompanied this morning by Assistant Secretary Kurzman and by Doctor Edwards, Doctor Stone and Dr. Rauscher, and we would be glad to try to answer your questions, or the questions of the committee.

Senator KENNEDY. Thank you very much.

I think there is basically a point of disagreement about whether the centers cover the 80 percent of the people that you indicated here.

I am going to leave that to the demographers. But as you are aware the Cancer Institute report points out that 53 million Americans are within 60 miles of a comprehensive center, and 98 million are within 120.

If you accept that the population is about 220 million, less than 50 percent are within reasonable access to the current number of centers that are planned.

Your figures are different, and if you want to provide additional information to support your contention, we will welcome it.

Mr. WEINBERGER. We can each consult our writers and find out who is right.

Senator KENNEDY. Is it primarily then a budgetary consideration that limits your support for additional centers?

Mr. WEINBERGER. No. I think it is more proper allocation of resources that is involved in that. The construction of several additional centers, we do not believe, will advance the effort quite as far as putting more money into the research and the demonstration, and into the delivery of the research results, and even at $600 million, some consideration has to be given to the proper way to allocate those sums.

This represents, I believe, the consensus of view that we have been able to establish, that 18 is a sufficient number, and will do very well considering that there will be these additional ones on the line by July, and that the remaining part of the resources should not go into the construction, or that kind of thing, but should go into more of the effort to find causes and cures and rehabilitation, and that sort of thing.

Senator KENNEDY. Your recommendations therefore, are given within the framework of the $600 million budget figure that is being submitted.

Is this the position of the Cancer Panel?

Mr. WEINBERGER. Mr. Chairman, as far as I know, yes. Doctor Rauscher is here, and he can certainly testify.

Senator KENNEDY. I understand that the Cancer Panel wanted to eliminate the limitation on the number of centers.

Mr. WEINBERGER. They may very well have. What I was trying to present was a consensus, the view of the Department, the National Institutes of Health, and the National Cancer Institute, as to the best way to allocate these resources.

Senator KENNEDY. $600 million?

Mr. WEINBERGER. Yes.

Senator KENNEDY. As I understand it therefore, with a budgetary figure of $600 million, you would not request more centers.

Mr. WEINBERGER. Well, I personally would think, and others are here who can testify to that, if we do not have some kind of basic limitation and basic plan in mind as to what you are going to do, and if you have a completely unlimited figure, the process would develop very shortly into something we are familiar with.

You would have a tremendous amount of pressure to have a center in each of the various districts and States, and it would be perhaps felt that it would have to be granted without respect to scientific needs for that kind of expansion.

So we believe that the number we have in place now, and the limitation, are both desirable bases on which to operate.

Senator KENNEDY. Am I correct that if there is a scientific justification for the new centers, you have no objection to authorizing them.

Mr. WEINBERGER. No, none whatever. We are told, and my belief on the basis of that advice is that the 18, which we will have in place by July, is a sufficient number at this time.

Again, as with other matters of this kind, if there should be any feeling of justification for additional centers to do work that cannot be done at the 18, we would not have the slightest hesitancy in asking, nor would we have any problem with the resources to fund them.

This is not a matter of saving money. It is a matter of best deployment of some very ample and substantial resources.

Senator KENNEDY. I think this is why we think it to be of great value to hear from the panels themselves. They have considerable expertise in this area and I think they have some definite ideas about the potential for manpower and research in these areas. We are obviously not interested in just authorizing money or just building facilities.

We want to make sure that every dollar in this program is maximized.

But I think if the case is made for justification of additional centers by those who have a primary responsibility in advising in this area, that will be very compelling testimony.

I think we should develop this point, and if there are any other questions, we can have them now. I will then have other questions.

Senator Schweiker.

Senator SCHWEIKER. The point I want to discuss with the Secretary relates to the $100 million increase for cancer, which I am pleased to see. I am glad to see the administration has upped the commitment.

I guess my question is, will this be totally new money? We will not be taking it from the other National Institutes of Health, and giving it to cancer?

I, unlike some of my colleagues here, wear two hats, being on the Appropriations Committee and the Health Subcommittee. I am delighted to hear the Secretary's opinion of the professional skill of the Appropriations Committee.

One of the problems we ran into last fiscal year was that with the exception of increases in heart and cancer, all the other Institutes of Health decreased from what was spent the year before, and also from what Congress had appropriated.

So I guess my key question is, is the $100 million going to represent another readjustment whereby the Institutes other than, say, heart and cancer, are going to take a cutback from the new 1974 HEW appropriation that just passed, or is this going to really be new money?

Mr. WEINBERGER. A quick answer to your question is, no, it is not being taken from other Institutes. There will be, I think—I do not have the authority this morning to reveal more than the budget request for the Cancer Institute—but I think you will find when the budget is delivered to the Congress next Monday, I believe, that you will be, I hope, pleased and reassured on that point.

You do, however, make an important point that we have to keep in mind, and that I know you do, as a member of the Appropriations Committee, and that is that there are a great many other Governmental activities, many of them have very high importance, also, although cancer does have the highest health priority of the administration.

As is the case with the appropriations for this particular item, the appropriations that we could make for all the other activities in the Government, is finite and limited.

So all of these things have to be considered against the overall background and overall total.

There is another programmatic reason for doing that. That is, the work that is done in the National Cancer Institute is not only of benefit in trying to eliminate cancer, it has a very important carryover to the work that is done in the Heart Institute, and in many others.

Whenever we study the circulation of the blood in the Heart Institute, it is bound to be some help to the people primarily interested in cancer.

When the cancer people study cellular structure, that too has some carryover for other people in other disciplines.

We have to consider the health program of the Government as a whole, and we do have to have in mind that when we ask for a very substantial sum for cancer, that is fully, we think, and completely justified.

We also think that it can be reflected in some of the results that may well benefit people working in other diseases and in other fields, and exactly the same thing happens in reverse when we ask for very substantial sums which we will ask for for the heart research effort, some of that inevitably, perhaps indirectly, sometimes directly, will benefit the cancer effort.

Putting strict boundary lines around these dollar and cents figures is not accurate.

But to answer your question, no, the increased request for the Cancer Institute will not cause a reduction in other Institutes. It does not change basically the overall requirement that we have to look at the entire health program for the Federal Government, for the nation, and we do ultimately have to look at all the available areas for the deployment of the total Federal resources.

Senator SCHWEIKER. As I understand what you are saying, it is that the $100 million increase will not be at the expense of the other Institutes?

Mr. WEINBERGER. I think that is perfectly correct, yes, sir.

Senator KENNNEDY. Senator Javits.

Senator JAVITS. Just one question.

I have already asked the principal question.

Mr. Secretary, the panel which is headed by the distinguished New Yorker, who Senator Kennedy and I had the honor of bringing into this effort—and the country has been blessed for it—Benno Schmidt, is the Chairman of the President's Cancer Panel.

Now, you are the President's department. The panel recommends this bill to us, including a number of things that you oppose.

What is the administration's policy on this matter? Who makes it?

Mr. WEINBERGER. Senator, I will not say you will have to accept, but I will say you can accept the presentation made this morning as reflecting administration policy.

We have, at last count, something under 370 advisory committees. We used to have 490, or something, and they all do very valuable and useful work, and I certainly share with you the high opinion you have expressed of Benno Schmidt.

The minor changes, as I see them, that are recommended in the bill that we have presented this morning, represent administration policy and the administration request for changes in this bill.

You will undoubtedly have many citizens from many other groups, some of them as Government advisory groups, some of them non-Governmental groups, who may suggest other changes, or may suggest leaving the bill alone.

I feel confident in stating to you that the changes we have requested are changes requested by the administration, just as I felt confident in reading the President's letter to you this morning.

Senator JAVITS. Mr. Secretary, the reason for my question is that this—I think I recall the situation correctly—is a different situation. We do have a National Cancer Advisory Board in this field. We also have the President's Panel.

The President's Panel—and I as one of the conferees—was expressly designed to exercise influence on the administration, the Presidency, with respect to this high priority crash program, which was the reason for the whole exercise.

I would have thought that the panel, as distinguished from the Advisory Board or the Department, would express administration policy. But it is a fact that this Panel is another level not normally present. It is a fact, also, that I would assume the independence of the Panel, and therefore, conceivably it could make a recommendation which the administration, through you—and I do not challenge your authority in any way—might not particularly agree with.

But do you not think, Mr. Secretary, that we would then have a right to inquire of the Panel what is really its function, if it is nothing but a supervisory committee, since we have an Advisory Board.

Could you tell us, therefore, as a corollary question, whether you think the panel should be preserved; and if so, why? What does it do that is different from the Advisory Board, in your opinion?

Mr. WEINBERGER. Well, Senator, the Panel does have a special function, and we, by working with them, and working with the National Cancer Institute, have evolved what we consider to be a satisfactory and very good working relationship that because of the good will of various individuals involved does seem to be working well at this point.

As far as their special function is concerned, it is set forth in the conference report, and the statute, and I would not wish to either challenge it or to characterize it, but to simply allow it to speak for itself.

Senator Javits. I will pass now, because I do not have the recital before me, but I think we ought to read into the record what the Advisory Panel does, and really test out whether that function is not duplicative of the Advisory Board.

Do you have it in front of you?

Mr. Weinberger. I have the language, yes, sir.

It says that the panel shall monitor the development and execution of the national cancer program under this section, and shall report directly to the President. Any delays or blockages of the execution of the program shall immediately be brought to the attention of the President.

The panel should submit to the President periodic progress reports on the program, annually, an evaluation of the efficacy of the program, and suggestions for improvements, and shall submit such other reports as the President shall direct.

At the request of the President it shall submit for his consideration a list of names of persons for consideration for appointment as the Director of the National Cancer Institute.

In other words, Senator, I think the characterization I made earlier is basically accurate that the President receives recommendations and suggestions from him. He receives them from many people. He embodies these recommendations in his decisions, and in authorizing us to present his recommendations with respect to the legislation and his budget request.

Senator Javits. This is, however, a unique function in Advisory Boards throughout the Department. To pinpoint this, would you say it is fair that it has three major functions?

One, to monitor the operations, both of the Department and of the Advisory Board?

In other words, it goes both below and above?

Mr. Weinberger. It says, "Shall monitor the development and execution of the National Cancer Program."

I suppose to the extent that the Advisory Board is considered part of the program, yes.

Senator Javits. It goes below the Advisory Board and above the Department.

Secondly, to submit names for top man in the effort.

Mr. Weinberger. Right.

Senator Javits. Third, to submit such other recommendations and ideas as its work in one and two may dictate?

Mr. Weinberger. To the President, yes, sir.

Senator Javits. Then the President may propose, or dispose?

Mr. Weinberger. Yes.

Senator Javits. Do you favor now that as we have defined it—and you do have this difference—I do not think it is a very deep difference, but it is a difference between the administration and the panel—do you favor the continuation of the panel, feeling that in this case because of the crash nature of the program, this kind of a special agency is necessary?

Mr. Weinberger. Well, Senator, I have, as far as this morning is concerned, I have no suggestions to make for organizational or structural changes in the cancer program.

As I say, I think it is working well, because there are many men of good will at all levels involved in it. I think if men of good will want to achieve a good result, they can overcome any organizational problems, or indeed, any organizational structure.

I would not have any recommendations to the committee to make this morning, because when the thing is working well, I do not feel any doctrinaire necessity to recommend changes.

Senator JAVITS. You do imply some doubts about the organizational structure.

Mr. WEINBERGER. I thought I was very careful not to say so.

Senator JAVITS. You do not wish to imply that? You are satisfied with it just as it is?

Mr. WEINBERGER. I thought the statement I made was one that I wanted to have in the record, Senator.

Senator JAVITS. Good. I am asking you another question.

Flatly, directly, are you satisfied with it as it is?

Mr. WEINBERGER. I am satisfied with the way it is working now, because as I say, men of good will who want it to work are addressing themselves assiduously to that. I judge things by how well they are working. This one at the moment is working very well. I have no recommendations as a result to make to the committee on organizational or structural changes.

Senator JAVITS. Thank you.

Senator DOMINICK. Mr. Secretary, I have received information, and I just want to verify this one way or another, that NIH at the moment has received and approved more planning grants than funds are available.

In funding plans for the centers, they will have to establish some more priorities, unless more funds are available.

Would additional funds coming in, if this is true, be available for planning grants, as well as the actual support of centers when they are finally approved?

Mr. WEINBERGER. In the proposed budget for 1975, Senator, we would have an increased amount recommended for the Cancer Centers support. We do feel that the 18 that will be on the line by July 1 is an adequate amount, and if I had more money available in the budget, I would not recommend that more be deployed for bringing onto line more than the 18 centers.

I have no doubt at all that there are, and always will be, a great many more applications than funds, but I suggest that the existence of an application on file does not automatically establish the need.

Senator DOMINICK. I understand that. I am not being critical.

What I am saying is that we are referring here to money for planning grants which have been approved. If you have got a planning grant which has been approved, and the funds have not been available to go forward with planning, there is a little problem there.

Mr. WEINBERGER. The 1975 budget will contain an increase for virtually every item, including planning grants, as I understand it, and for that reason there would be more funds available for planning grants in 1975 than in fiscal year 1974.

Senator DOMINICK. That is what I wanted to find out.

Thank you very much.

Senator KENNEDY. Senator Beall.

Senator BEALL. Thank you, Mr. Chairman.

I do not want to belabor the point, but Senator Schweiker brought up a matter of some interest to me. I think we are all naturally pleased to have the emphasis placed on cancer and the heart.

Obviously, the devastation caused, particularly by cancer, is something that needs national attention.

I saw some statistics recently that indicate that since the year 1968 through this past fiscal year the total obligations to the National Institutes of Health have increased by 41 percent. But if you take, or exclude the money, the obligations for cancer and heart institutes, the total obligations for the other institutes collectively have increased only 3 percent.

As a matter of fact, if you include a 5 percent inflation factor, the total obligation for those Institutes have actually decreased by 24 percent.

This would seem to indicate to me that there is a major change in emphasis toward cancer and heart. I am not complaining about the emphasis, but I am wondering if this is not really at the expense of some of the other Institutes.

There has been a 24 percent decrease for some of the other Institutes——

Mr. WEINBERGER. I do not believe there has been a decrease at all. I think there has been a leveling off. I think this is the inevitable result of an activity that had previously had a growth rate of approximately that of the Japanese economy, something in excess of 25 percent each year for many years, inevitably any such activity is going to have to level out.

The specific question that Senator Schweiker addressed to me is with respect to the 1975 budget and my response to him was that the addition for cancer did not disrupt or lower the planned requests for the other Institutes, and that is an accurate answer.

But the question you address is whether all the other Institutes of the National Institutes of Health should increase at the same steady rate of progression that has been the case in the past, and I suppose that the administration's answer to that simply is that the total funds overall, governmentwide, given the uncontrollability of so many other programs are just not available for that kind of an increase.

On the other hand, I do think that the point I made a moment ago is a valid one, and that is that work done in arthritis, work done in heart, work done in cancer, has a carryover effect back and forth to all of the Institutes and the national health effort, and that we should not ignore that, nor should we feel that simply because cancer is the highest priority, and heart is the second highest priority of the administration, that the work done in those fields is of no benefit to the health of the Nation generally.

I think it is tremendously beneficial, even though it may not be directly involved in additional work on, let us say, arthritis or general medicine, or some of the other aspects of the Institute's work.

Senator Beall. I am not disputing that statement, I am in general agreement on it. I am not even suggesting by the question that the other Institutes should increase at the same rate they have been increasing in previous years.

But maybe because the NIH headquarters is in my own State, I have received more mail concerning this installation than others would, but I continue to get letters from people who are employed there in research capacities showing some concern about the way decisions are being made, and where emphasis is being placed.

You cannot help but notice when people like the Assistant Director, who recently resigned, indicated in his statement that the effectiveness of the Institute is being impaired, or that there is an atmosphere of despair around —I am wondering if this does not relate to the way the money is being spent at the Institute?

Mr. Weinberger. Senator, I would strongly dispute that, and even more strongly disagree with the resigned former Deputy Director.

I do not think there is any connection whatever between the two. It is unquestionably true that a person who works in a particular field, and who has no responsibility, or indeed knowledge, or willingness to examine the overall problem of the health picture, or of the entire governmental structure would feel aggrieved if his particular specialty is not increased by the amount that he would like.

As you know, from your years of service, there is never a request that can be honored in full. Every request is always heavily inflated, and the ultimate result is something that the process, Congress and the executive branch, working together, ultimately resolve.

Inevitably, in our kind of government, it is going to be something that leaves everybody less than satisfied. I would not be surprised if there are some cancer people who wanted a lot more than $600 million.

I would not be surprised if there were some heart people who want a lot more for the budget request for them in 1975.

Certainly it is true of every form of governmental activity with which I have ever been associated, that the initial request was always higher than the amount that can be allotted.

I do not think there is any basis for despair, or outrage, or the other common words that are used so freely.

The NIH is not in my own State. But I get a lot of mail from it, too, and I sense a very improved spirit.

Dr. Stone is here, and Dr. Rauscher is here. We would be delighted to have either or both of them respond to this question about the general attitude out there.

I think that the work that is being done there is enormously important. It is extremely vital that we fund it at the very high level that we are funding it, and that we continue to fund it.

And the increases that will be requested in 1975, they will not be as much as people intimately concerned with individual details of each Institute would like to have, but that is inevitable, and I think is a permanent condition.

Senator Beall. While I would like to pursue the funding and other policies, I will not do it today. But we are here on a specific matter, and I would like to pursue this. I want you to know that I plan soon to go out to the Institute and see for myself, firsthand, what is going on, and get some feel for the feeling of the people there.

Let me ask one other question on another subject.

You have the authority to carry over funds from one year to another, don't you?

Mr. WEINBERGER. Depending on the language in the appropriation bill, but the answer generally is yes.

Senator BEALL. You generally do have that authority?

Mr. WEINBERGER. Yes. One full year is carried over to the end of the Appropriation Act.

Senator BEALL. A researcher then is not compelled to spend all of his grant in the year in which he gets it?

Mr. WEINBERGER. No. We think it is very important that he not be.

Again, we do not think we should measure results by total amount spent in any 1 year.

Senator BEALL. I agree with that.

We ran into a similar problem in education, and we came up with a provision for carryover.

Senator KENNEDY. Senator Pell.

Senator PELL. I had a chance to peruse the statement of the Secretary, and there is one subject that is of particular interest to me, a matter which was enacted into law, and that is the provision in the Cancer Act, saying that the NCI shall "collect, analyze, and disseminate all data useful in the prevention, diagnosis, and treatment of cancer, including the establishment of an International Cancer Research Data Bank, to collect, catalogue, store, and disseminate insofar as feasible the results of cancer research undertaken in any country for the use of any person involved in cancer research in any country."

The purpose here, as you may recall, was to reflect that we do not have a monopoly on all medical knowledge. Many of the same experiments may be run in Russia, Germany, Britain, France, Japan, and other technologically advanced nations, and some of these experiments may produce useful information.

If we knew about them, we would save time here, and some failures. Some tests may have been run there, and by not knowing about it, we may run through the same tests here.

I am very distressed to find very little real movement along the systems approach for building international data research banks.

The only reference in your statement was on page 6, when you mentioned the Telex line between the United States and the Soviet Union.

I was wondering if you could tell our subcommittee, first, why there has been no substantive movement in the direction which you were mandated to follow; and, second, what your plans are for fulfilling this mandate?

Mr. WEINBERGER. Senator, I would dispute strongly your assumption that there has been no progress, or there has been no carrying out of this mandate. There has been a very substantial carrying out of this mandate.

I had the opportunity this summer, when I was in the Soviet Union, to examine fairly thoroughly a lot of the cancer efforts in

Soviet Russia. They are substantial, and they are very closely correlated with the efforts in our country, as is the case in many other countries where this important work is going forward.

We mentioned the Telex line, because that was a matter of agreement between the two governments, and one of the reasons they wanted to have it was so that there would be a much more rapid exchange of data than would otherwise be the case.

Otherwise, if it was stored in some computers, and printouts made eventually, and computer capability there is not equivalent to ours, so that you would have a much slower exchange of information.

We are carrying out the mandate of the act. We are exchanging both information and scientists, and actual samples of tissue and drugs, and we are doing it with a number of countries.

I think the assumption, or the statement that we are not carrying out the mandate in this connection is quite unwarranted.

There are others here who can testify in more detail perhaps to it, but we recognize fully the work that is done there, just as those countries recognize the importance of the work done in this country.

They are very eager to have an exchange. They are doing that. We also have efforts underway to improve the exchangeability of the information that is gathered at the National Library of Medicine with a number of countries.

In all of these ways the mandate of the act is being carried out. The fact that there may not be a separate building, with a label on it, headed the International Cancer Research Data Bank, should not be taken as any kind of indication that we are not aware of, or do not support the necessity of exchange of information with all these other countries that are also doing very valuable work, and who want the information about the work we are doing.

Senator PELL. Well, what you have described so far is an extension of what we were doing before.

I have yet to hear from you about the system's center.

As you look at the legislative background of this amendment, the statements of Mr. Schmidt, and the advisory committee of the council that he headed, you will see my statement stands. As you say, naturally, when you travel, there is an exchange of documents and information and always has been, but what we are talking about is a single systems center where all these tests are run into a computer and where you have the universities, our own hospitals, and our own research people here with data systems that can feed into a tube and find out what has been run before and what has not, and in this particular regard, the establishment of an international cancer research data bank, no progress has been made whatsoever.

Mr. WEINBERGER. I think that is not correct. There has been great progress made, Senator, and my understanding is that our data center in this country is the National Cancer Institute and it exchanges information which it gathers through its Registry and others around the country with information that is gathered similarly from the Institute of Oncology in Moscow.

Dr. Rauscher may want to develop that further and also Dr. Edwards.

The structure of the act is being carried out.

Senator PELL. As you look back on the hearings we had and the discussions the idea was to tie it into a computer so the man in Chicago can press his buttons there and get back what the results were in Russia or Germany and there has been no move in that direction; am I correct?

Dr. RAUSCHER. Senator, let me speak to that.

No. There has been a great deal of new activity in this area. One of the first activities that was conducted was to determine where data banks already existed not only in this country but in the world.

The idea there, of course, was trying to take advantage of things already developed. This has been done. I can identify three in France, Germany, and England.

The Secretary has already commented about the data system in the Soviet Union.

What we are trying to do is develop a data system where we can get data out of each of these in a very convenient and time saving way.

The other new activity as an example is our support of the International Agency for Research on Cancer in France to serve literally as a world repository.

Now, this is brand new and a very important component of the International Cancer Research Data Bank.

In this country, the National Cancer Institute in Bethesda serves as the major quarterback, if you will, for all these data systems.

There are other principal components of this, however. For instance we have private studies going on now in the Pacific Northwest Center, in the Fred Hutchinson Cancer Center, as well as another one for the Rocky Mountain area centered in Denver whereby all available information that can be of benefit to any physician is now being put not only on tape but already being stored in computers.

Another component of this has to do with the dial access system. A member for instance of the President's Cancer Panel, Dr. Lee Clark, has been very much interested in this and has developed a system as have others in the country whereby physicians can call and find out what is the latest mode of treatment or the best method of treatment for a particular cancer.

This is followed up within 24 hours with a written printout to that physician. These are all components of the data bank. They are all new components that were initiated really since the passage of this act and a great deal of activity has been going on.

Senator PELL. To be specific, can Dr. DeBakey in Texas ask his computer has such and such an experiment been run in the Soviet Union from your data bank?

I do not think that is possible. Can you do that?

Dr. RAUSCHER. Not yet in that way. He can still get the information by calling us at the Cancer Institute to find out if that experiment has been performed.

Mr. WEINBERGER. In Dr. DeBakey's case he would be able to get it more directly because he is involved with Dr. Petrovsky, the Minister of Health in the Soviet Union working on this joint authorship and he has a very direct opportunity to communicate and would be perfectly authorized to use our Telex for information of that kind.

Senator Pell. When do you believe you will have, at the rate you are moving now, a true international cancer research data bank to collect, catalog, store, and disseminate information?

Mr. Weinberger. A great deal will depend on the progress made in other countries.

This does not depend on our own technology alone.

Dr. Rauscher may have an exact time estimate. But a great deal depends on how rapidly they advance their own techniques and their ability to collect and centralize the information done in their countries and place it on the computer.

Senator Pell. When do you think you will have such a data bank just for ourselves in the United States?

Dr. Rauscher. I think we have a data bank at the present time for the United States.

There really is no trouble getting the kind of information which is very expensive. Most scientists tell me they have enough information now.

Senator Pell. When do you think this system will be related to the other countries in the world?

Dr. Rauscher. I think for the Soviet Union we are progressing very rapidly and to be specific within the next 8 to 10 months.

Senator Pell. How about Germany, France, and Great Britain?

Dr. Rauscher. France is about 50 percent. Again, to be precise, there is a long way to go between the United States and France.

We have just signed an agreement also with the Japanese. Our second meeting will be held this spring again with the idea of getting the Japanese data plugged into the international data bank.

Senator Pell. Will this be done by computer, and not just by typing a letter?

Dr. Rauscher. It will be done through a Telex system with computer storage data.

The computer is the only way to do this, of course. It is the major way.

Senator Pell. The major way?

Dr. Rauscher. Yes, it is.

Senator Pell. And you say that within 2 years we will have a true international data bank established?

Dr. Rauscher. I think we already have some major components of the international data bank.

In terms of the complete collection, analysis, dissemination of data, this is a matter of 2, 3, or 5 years.

Senator Pell. I still do not understand clearly what you are saying.

When will we be able to acquire information about a serious experiment that has been done and is being run through in Germany, and know if it is a failure or success?

When will that be able to be retrieved immediately?

Mr. Weinberger. We can do that now. It is a question first of all whether every doctor in this country is going to be equipped with a computer in his own office. If you want to know the results of an experiment in Germany we are perfectly equipped to get that information back from Germany to the doctor who makes his request to the Institute somewhere in the neighborhood of 24 hours, or maybe 48 hours, depending on how rapidly they can get the answer in Germany.

The centralized points of inquiry and distribution information are established, for the most part.

We can go back this afternoon and tap out a message on the Telex and inquire of the results of some experiment involving some powerful chemotherapy in Russia and if they have the information, it will come back in this afternoon and we can pass it on to Texas, Rhode Island, or wherever the particular doctor is who wants to know. But the ultimate link of a doctor sitting in his office in San Francisco and typing out something and getting an immediate answer back from Moscow is probably a few years off mostly because a great many doctors in San Francisco are not going to have computers in their offices, but the ability to get that kind of an answer in a very short time is there now for the most part and to a great extent it will depend on the ability of the foreign countries with whom we are dealing to collect the information internationally themselves.

In Russia, as Dr. Rauscher has said, the system is very more centralized, and they are able to get that kind of information very quickly. They do not have a voluntary system and can get it very rapidly.

Senator Pell. Who is the Chairman or Director of your International Data Research Bank now?

Mr. Weinberger. Where, here?

Dr. Rauscher. He is an Associate Director of the National Cancer Institute, Dr. O'Conor. He is a pathologist and an expert in international cancer activities.

Senator Pell. Thank you.

Senator Kennedy. Perhaps we could get a report from him along the lines of Senator Pell's inquiry to give us a detailed memorandum as to exactly what is being done, if that is agreeable.

Senator Pell. That will be fine, Mr. Chairman.

Mr. Weinberger. The President's panel has noted some very flattering aspects of the work also.

Senator Kennedy. Senator Taft?

Senator Taft. Thank you, Mr. Chairman.

One of the bases on which the legislation we are discussing this morning was set up was a feeling of mine and I think a feeling of many other Senators that its purposes were several. One was to assure a constituency to direct attention to the point of view of getting assurance of continued, adequate financing and an increase in financing if necessary, to bring about effective research. And we seem to have more or less moved on that objective and where we find ourselves this morning bears out the wisdom of that decision.

It was also a theory that this setting up of a separate institute was the most effective way of assuring maximum progress in research in cancer.

I have heard criticisms of that decision and questioning as to whether or not that actually has occurred as a result of the approach that we took, the setting up of a separate National Cancer Institute.

What I would really like to ask is just one basic question—Is the approach that we have taken of setting up the National Cancer

Institute adequately interdisciplinary to assure that we are making maximum progress in research in cancer?

And, secondly, are we getting the maximum benefit from that research in noncancer-related diseases, as well?

Mr. WEINBERGER. Senator, I think you put your finger on a very important point in asking an extremely important question, and I would answer it by saying I believe that the work of the National Cancer Institute is interdisciplinary primarily because of the good will of the numbers of people who are participating in it.

I think the organizational structure if it were replicated throughout the entire Government would have obvious disadvantages and would tend to compartmentalize everything and prevent an overall examination of the related aspects of a lot of the work that we are trying to do, not only in health but elsewhere.

It is certainly enough emphasizing and underlying the importance and priority which the administration and the Congress attaches, and properly so, to cancer. But it is quite possible that if it were not being run under this pattern and this organizational structure by men of good will who want to agree and who want to work out results and who want not to have isolation result from this kind of organizational structure that we might be running into those dangers. However, I think it is quite correct to say that one of our major thrusts with respect to the National Institutes of Health has been to assure that the work is entirely interdisciplinary.

Mr. Chairman, that is one of the reasons it is so important to have the entire research effort under general overall direction and supervision and management of the Institute.

Dr. Stone is here and can testify as to our own desires that that happen and that there be proper carryover.

As to the way in which he tries to assure that that does happen, and I think it is happening with respect to cancer and the work of the National Cancer Institute, and I think the fact that it is a very real tribute to the people involved on all aspects of this, maybe Dr. Stone would like to add a word or two.

Dr. STONE. Senator, I would only supplement the Secretary's remarks in one regard, and that is I am extremely pleased that the administration has taken this opportunity to make a very strong statement on behalf of basic medical research.

That is the source of information for all of the Institutes and that has a kind of compatibility, a kind of interchangeability, a kind of diffusion that occurs regardless of institutional boundaries.

As long as we put great effort into that basic medical research I think we are safe.

Mr. WEINBERGER. I would like to emphasize, Senator, that we do plan and are planning to put a great effort into basic medical research.

We believe it is proper to have a balance between that and research that is specifically focused on trying to develop particular needs and things of that kind.

We have not the slightest intention of reducing or eliminating or in any way weakening any basic research thrust sponsored by the Federal Government.

Senator TAFT. Thank you, very much.

I gather that the answer is, it is something that appears to be satisfactory at the moment but should continue to be monitored.

Mr. WEINBERGER. Yes, that is the gist of the answer I tried to give to Senator Javits and that is my feeling.

Senator KENNEDY. I have some questions for Dr. Rauscher.

Has your budget channel procedure worked well?

Dr. RAUSCHER. It has worked very well, Mr. Chairman.

Senator KENNEDY. And you have submitted your budget directly to the White House and gotten your funds from OMB directly?

Dr. RAUSCHER. We submit our funds directly to the Office of Management and Budget with concurrent copies to Dr. Stone and to the Department.

That has worked very well.

Senator KENNEDY. How many personnel positions have you requested in order to fill out your mandate in the cancer program?

Dr. RAUSCHER. I have been very concerned about the availability of an adequate manpower base to effectively manage the dollars we are getting into cancer all over the country and have requested additional positions from the Office of Management and Budget with support from the Department.

I am very pleased to say quite recently we did receive an additional number of positions.

Senator KENNEDY. How many did you request?

Dr. RAUSCHER. I requested a minimum of 109 positions.

Senator KENNEDY. When did you make that request?

Dr. RAUSCHER. About a month ago.

Senator KENNEDY. And how many have your received?

Dr. RAUSCHER. We will be authorized, it is my understanding, to recruit virtually up to that level over a 2 fiscal year period beginning with this fiscal year.

I do not know what the exact distribution will be in 1974 and 1975, yet.

Senator KENNEDY. You had requested for just 1 year and now you will be able to get the full complement over a 2-year period?

Dr. RAUSCHER. My major concern was to have as many positions as we needed as a minimum right now and I think we will get them.

I have been told that these positions are up and forthcoming.

Senator KENNEDY. Who has told you that?

Dr. RAUSCHER. This is word from the Under Secretary and from the Assistant Secretary as well as from OMB.

Mr. WEINBERGER. I can confirm that.

Senator KENNEDY. That they will get those positions?

Mr. WEINBERGER. Yes.

Senator KENNEDY. Mr. Secretary, if this direct budgeting process appears to have worked so well in regard to cancer, why not develop a similar system for the rest of NIH to guard against what has been I think the legitimate concern of Senator Schweiker, Senator Pell, and a number of us over a period of time; that is, the cutting back of the other Institutes.

Mr. WEINBERGER. Senator, that is a system that can only work when there is no concern whatever about the total expenditures each year of the Government.

Senator KENNEDY. I do not think that is very responsive.

Do you want the record to reflect that answer as a response?

Mr. WEINBERGER. It cannot be more responsive or specific than that. You cannot have that kind of system unless you have no concern about the overall total that the Government spends.

If you have any concern about that and its effect on the inflation and the tax burden people have to have, then you have to have some overall consideration of the total requests. And those I think have to initiate generally with the departments that are most concerned with those activities. Otherwise, you have something like 1,500 or 1,800 separate units going in with their own separate budget and I do not think that kind of system would work.

We have tried it on a much smaller scale prior to 1921 and ever since then the feeling has been that we needed some kind of overall approach.

It is actually the system that has produced an increase in the NIH budgeting from something under $5 million to about $2 billion now.

It has not worked in all that restrictive a fashion but it does have to have I think some kind of overall examination and otherwise each individual program, each individual Institute, the person who felt he was not getting all he felt he was entitled to would run this independent route and we would have quite a problem.

Senator KENNEDY. Any Institute staff would obviously have to justify such a request. Why would you not expect them to adopt a responsible attitude?

Mr. WEINBERGER. It is a question of whom are they going to justify it to and what would be the criteria used.

Generally speaking among people who are primarily interested, and I do not say it critically, people with primary interest justify it by saying they need it and they do not have an independent examination made of their need measured against a total background of availability of resources. And if, as I say, there is no concern whatever about the overall total that the Government spends, then it is a system that conceivably could work, that you just add up a list of demands, but it is not a system that can work where you have to have some concern as to what the Government spends or the people pay in taxes or the effect on the economy, etc.

Senator KENNEDY. Of course, OMB would still be available to exercise some judgment.

Mr. WEINBERGER. Well, they are fairly heavily burdened now and if there is no screening in advance of OMB I would think the protest against OMB would rise to such a pitch of volume that they would be abolished within 6 months.

Senator KENNEDY. To some that might appear desirable.

Mr. WEINBERGER. To some that is a temptation but I do not hold it out to you as a hope.

I think you would find the tax rate would be completely insupportable, particularly for the elected officials, and you just could not have that kind of system and expect to have any kind of built-in self restraints.

Senator KENNEDY. I think you would be surprised at the number of Americans who would be willing to pay more taxes if more money were to go to improved health care.

Mr. WEINBERGER. One question to be answered is, what are they getting for that money? And that is not showing them vastly increased totals each year without substantial improvements in results and I do not think that would satisfy very many of them. I do not think they would gladly bear this increased burden.

Senator KENNEDY. I think indications from the public over any period of time have shown strong support for allocating additional funds for these kinds of health programs. Obviously we are not suggesting the open-endedness you inferred in response to my question, but I think the American people would like to see these kinds of programs developed, and I think the American people would support additional allocations to do so.

Mr. WEINBERGER. What we are really talking about is the President's request, the administration's request of the Congress.

There is, as you know, nothing that prevents the Congress from adding to a Presidential request.

What we are talking about is the mechanics of preparing and organizing and considering the President's overall request for the Government as a whole, and if the Congress has different ideas as to the proper priorities, they have certainly not hesitated to exercise those in the past and I am sure would again.

I do not see any way in which you could apply this particular organizational structure to the Government as a whole and I think you would have very serious problems if you did it.

Indeed, it was those very problems when the Government was much smaller that led to the creation of the Budget and Accounting Act of 1921.

Senator KENNEDY. Excuse me, Mr. Secretary, I was not talking of the Government as a whole but of the National Institutes of Health.

Mr. WEINBERGER. There is every reason to believe that the precedent that would be established and extended and carried out because your very understandable and proper interest in health was replicated by your colleagues in every other field in which the Government is interested and I see no way in which we could present any logical arguments against doing the same thing in education or in welfare or in the environment or any one of a number of different fields.

[The prepared statement of Caspar Weinberger follows:]

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DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

STATEMENT

OF

CASPAR W. WEINBERGER

SECRETARY OF HEALTH, EDUCATION, AND WELFARE

BEFORE THE

SUBCOMMITTEE ON HEALTH

COMMITTEE ON LABOR AND PUBLIC WELFARE

UNITED STATES SENATE

Wednesday, January 30, 1974

MR. CHAIRMAN AND MEMBERS OF THE SUBCOMMITTEE:

I am pleased to be here to testify in support of the extension of the programs authorized by the National Cancer Act of 1971, the authorizations for which expire on June 30th of this year.

I would first, however, like to make a few introductory remarks, followed by a brief summary of progress since passage of the Act.

## Introduction

The Administration and Congress have both been deeply committed to the expanded cancer research program which was augmented in December 1971 when President Nixon signed the National Cancer Act. Our joint efforts in these areas have indeed provided an excellent example of the ability of the Executive and Legislative branches to work together in dealing with a major problem.

Cancer, in its more than 100 forms, still constitutes a devastating health problem for the citizens of this country and, indeed, for mankind everywhere. Cancer continues to be the second leading cause of death in this country and the incidence of new cases continues to increase.

Yet the outlook is improving at a steadily accelerating pace. One out of every three persons who now have cancer can expect to be alive five years after treatment. There are one and a half million Americans who have had cancer but are now well. An additional one million cancer patients diagnosed and treated in the last five years are expected to live to join these ranks.

Much of this progress and the hope for the future is a result of the increased emphasis of the cancer research effort as administered by the NCI and the NIH, in cooperation with many private and public groups. This effort has a dual mission. The first is to speed the development of new knowledge by an intensive and coordinated research effort involving the broad scope of medical, biological, chemical, and physical sciences. The second is to demonstrate the most effective methods for the prevention and control of cancer through dissemination and educational activities. This demonstration of research results applies the best of our present knowledge and will provide for the rapid application of new information as the national cancer research effort continues to gather momentum.

Progress

This dual approach has resulted in much progress, which has brought us closer to the answers we need. This progress has been the product of cooperative public and private efforts in the areas of cancer cause and prevention, detection and diagnosis, treatment, and rehabilitation.

We do not expect that there will ever be a single cure for the many forms of cancer. Instead, scientists and physicians are exploring all promising avenues of research that may lead to identifying the causes of cancer, preventing cancer whenever possible, diagnosing cancer earlier and more accurately, and treating it more effectively. The host of individual advances all work toward the ultimate goal of preventing the occurrence of cancer, curing cancer when it does occur, and restoring former cancer patients to full, productive lives.

To implement these programs more effectively, the National Cancer Institute has recently undergone a major reorganization to assist the Director in carrying out his new and additional responsibilities as Director of the National Cancer Institute. Mr. Chairman, I would like to submit for the record a chart depicting this organization.

I also would like to note the significant budgetary increases that have been provided. In 1971, the National Cancer Institute appropriation level was approximately $233 million. Today, the budget level has more than doubled. The 1974 appropriation would provide up to $551 million and additional increases will be requested for FY-75.

NCI operations are only one of the avenues of approach. The understanding of the abnormal growth and spread of cancer is inextricably linked to the biology of normal cells. The National Cancer Act recognized that, "the present state of our understanding of cancer is a consequence of broad advances across the full scope of the biomedical sciences." This ranges from the molecular biology of genetic control to the biochemistry of cell membranes, metabolism, and immunology. The National Institute of General Medical Sciences, the National Institute of Allergy and Infectious Diseases, the National Institute of Arthritis, Metabolism, and Digestive Diseases, along with the National Cancer Institute and the other Institutes, are responsible for exploring these fundamental life processes through support of basic research. These processes are still far from being fully understood.

The Administration's support of basic research was almost $400 million in 1973. Interaction between scientists of the various Institutes in the area of basic biomedical research and with the scientific community at large is intense. The clues to advances in cancer may well come from research done and supported by other Institutes just as clues to advances in their areas of responsibility may come from research done or supported by the NCI.

Increased participation in cancer research by scientists in industry and in educational and other non-profit institutions also has been achieved as called for by the Act. In 1971, NCI had 1096 active grants and 252 contracts with educational and other non-profit institutions, and there were 139 contracts with profit-making firms. In 1974, NCI will have an estimated 1,747 grants and 1045 contracts with educational and other non-profit institutions, as well as an estimated 216 contracts with profit-making firms.

The international scientific community has also been brought into the cancer research effort, as called for by the Act. Research in 19 foreign countries is being supported by NCI.

Especially noteworthy is the broad cooperative cancer effort that has taken root through the Joint U.S.-U.S.S.R. Health Agreement of 1972. One result of that agreement is the TELEX line which has enabled cancer scientists in the U.S. and the U.S.S.R. to communicate with each other daily since mid-October. This system is used to exchange information on such things as the use of drugs, the exchange of scientists, and the shipment of materials.

I would like to describe briefly some of the accomplishments against cancer which have been made.

## I. RESEARCH RESULTS TO DATE

First, in the research effort there is a new emphasis on developing treatment methods that effectively use combinations of surgery, radiation, and drug therapy.

As a result:

- Half of those children with acute lymphocytic leukemia, a cancer of the blood, now are alive five years after diagnosis when treated agressively with radiation and a combination of anti-cancer drugs. Twenty years ago, this disease struck down most of its victims within a few months.

. Radiotherapy for the early stages of Hodgkin's disease, another cancer of the circulatory system, produces five-year survival rates of more than 90 percent. This is compared to a 68 percent survival rate for early Hodgkin's disease five years ago. A four-drug combination treatment for advanced Hodgkin's gives a 65 percent survival rate after five years, a vast improvement over the survival rate of less than 10 percent five years ago.

. There are indications that breast cancer may yield eventually to a combination of drugs, surgery and radiation. Overall five-year survival rates for this disease, which kills more women than any other form of cancer, have remained near 60 percent for the past two decades. Scientists now have found significant decreases in tumor size when advanced breast cancer patients are treated with any one of six drugs. Although these observations do not show any lengthening of these patients' lives, they are essential first steps toward improved treatment for breast cancer in the future.

. Adriamycin, another experimental drug, has been found to have activity against a broader range of cancers than any other known drug. This includes breast cancer and lung cancer, the leading cancer killer among American men and now the third greatest cause of cancer deaths among women as well. Research now centers on developing less toxic forms of the promising drug.

Second, progress has been made in the early detection of cancer.

For example:

. X-ray examination used in combination with physical examination in studies of mass screening for breast cancer has resulted in a one-third reduction of the death rate from that disease over a five-year period for the individuals in that study.

. Another report in 1973 showed the value of periodic examinations for colon-rectal cancer, the second greatest cause of cancer deaths among both men and women. A study was conducted of 18,000 persons over age 50 who had over the past 25 years received periodic examinations of the lower colon, and removal of polyps or other pre-cancerous conditions.

The rate of colon cancer among these individuals was only 15 percent of that expected if they had not been examined regularly.

. Scientists are using immunologic techniques to detect cancer-related chemicals, or "markers," in the blood or urine of persons with cancer. One such marker, called carcinoembryonic antigen (CEA), may be useful in combination with other tests for cancers of the digestive system, particularly colon cancer.

Third, progress in understanding the causes of cancer may lead to its prevention as well.

In this regard:

. The National Cancer Institute has been able to step up its program to identify cancer-causing chemicals in the environment. Approximately 445 chemicals are now being tested in two-year and three-year studies with animals. The tests are under way at 20 laboratories, including the Frederick Cancer Research Center, converted by Presidential mandate from a biological warfare center, at Fort Detrick, Maryland.

. No virus has yet been found to cause human cancer, but scientists are accumulating evidence for some type of association of several viruses with breast cancer, leukemia, cancer of the cervix, and other forms of cancer. A battery of highly sensitive biochemical and immunologic tests have been developed for this research. These tests have been used to show that at least two suspected human cancer viruses are actually of animal origin, important information which allows NCI to direct its resources elsewhere.

Finally, several totally new approaches for cancer control and prevention may ultimately emerge from fundamental research into the life processes of cells.

These include:

. An artificial and potentially functioning gene has been synthesized for the first time. Years of further research may lie ahead, but scientists hope artificial genes can be used to learn how cancer starts--and how it can be stopped.

. Genes direct the synthesis of enzymes that cells need to function. There is new evidence for several enzymes that may appear only in cancer cells. If these enzymes are essential for cancer, blocking the enzymes may kill cancer cells while leaving normal cells unharmed.

## II. TRANSLATION OF RESEARCH RESULTS INTO MEDICAL PRACTICE

Turning to its second thrust, I am pleased to report that the National Cancer Institute, working with cancer centers around the country, has posted an excellent record in delivering research results to the people. We are doing what can be done, now, for the cancer patient and those at risk to cancer.

Nine major medical institutions across the country have established Comprehensive Cancer Centers. The remaining six Centers authorized by the National Cancer Act will join these ranks by July 1. In addition, three pre-existing Centers of comparable scope have been strengthened. These Centers engage in the full range of basic and clinical cancer research and teaching. They demonstrate and assist other institutions in their surrounding areas to provide the best possible programs of cancer prevention, detection, diagnosis, treatment and rehabilitation.

Cancer control activities, also called for by the National Cancer Act, have been firmly established. This new program is speeding the application of research advances through relatively short-term projects conducted in and out of major centers such as:

. In cooperation with the American Cancer Society, 20 breast cancer detection projects have been established throughout the country. More than 100,000 women will be screened annually to find breast cancers in the earliest possible state--when this leading cause of cancer death among American women is most curable.

. A network of more than 100 community hospitals is being established to demonstrate effective new treatments for acute lymphocytic leukemia, Hodgkin's disease and non-Hodgkin's lymphomas.

. Collaboration with the HEW National Clearinghouse for Smoking and Health is aimed at reducing the number of cancers caused by smoking.

. Several centers and hospitals are developing model cancer rehabilitation programs that can be replicated in community hospitals as well as in the large centers for cancer care.

The National Cancer Institute also conducts and supports clinical research involving all 36 major forms of cancer.

More than 20,000 patients, 1,600 physicians and 320 cancer centers and other hospitals throughout the country are participating in these programs. This is the frontline where new approaches are being tested for treating cancer.

## Description of S.2893

S.2893 would extend the appropriation authorization in the National Cancer Act of 1971 for three years raising the authorization levels to a total of $750 million in 1975, $830 million in 1976, and $985 million in 1977.

The bill would also make certain other changes in the Act. It would remove the statutory limitation of 15 new cancer research and demonstration centers. It would raise the authorization for scientific or expert consultants from 50 to 100. It would also expand the construction authority of the Act to include construction of non-clinical basic research facilities.

## Proposals for Change

The Administration and this Committee are, I believe, in full accord in our commitment to maintain the momentum of the cancer research effort. It has the highest health priority in this Administration. We do disagree on certain of the specifics of the approach to be taken. These differences arise from our need to consider it against the background of the total resources we have for other health research efforts and for other health programs as well.

We agree, as I have stated before, that the forward thrust must be maintained and enhanced. We would, however, ask that the following changes be incorporated into S.2893.

First, we believe that specific authorization levels for the Cancer Control Program and for the remainder of the program be deleted in favor of a single authorization, "such sums as may be necessary." We feel strongly that this language adds additional necessary flexibility to our efforts to manage the resources available for health programs. As noted earlier, the funding requested for FY-75 represents an increase over that appropriated in FY-74.

Secondly, we do not believe that additional categorical cancer centers beyond the 18 now established (15 new, 3 strengthened) should be constructed at this time. We feel that the existing three centers in addition to the 15 centers authorized in the Act constitute an adequate and effective demonstration effort. The National Cancer Institute estimates that 18 centers will provide outpatient care within a 60-mile range to approximately 45 percent of the U.S. population and inpatient care within a 120-mile range to over 80 percent of the population. With this amount of population covered, these centers can effectively carry out an essential mission of demonstrating the best methods of cancer treatment. To support any more of these centers would move the Federal Government dangerously close to a complete cancer-based treatment responsibility. This role would not only be an undesirable and unnecessary one for the Federal Government, but would create serious equity problems by providing special Federal subsidies on a categorical basis. We feel that the Federal Government's resources will be used far more appropriately and effectively against this serious health problem by concentrating on research and demonstration of effective modes of care.

The last two proposals in S.2893 (to delete the words "where appropriate" from Section 407(b)(7) and to increase the number of experts and consultants in Section 410(1) from 50 to 100) are not needed and would not enhance the operation of the National Cancer Institute. These proposals were suggested by an Ad Hoc Committee appointed by the National Cancer Advisory Board and have not been identified by the National Cancer Institute as creating administrative problems.

## Summary

In summary, Mr. Chairman, the Administration is pleased with the progress made by the expanded cancer research effort. We firmly support your efforts to continue the program and, with the changes which we have suggested, would be glad to support S.2893.

Mr. Chairman, that concludes my formal remarks. We would be pleased to answer any questions from you or your colleagues.

Senator KENNEDY. Senator Nelson?

Senator NELSON. I have a question for Dr. Edwards.

When the Cancer Act was before us a few years ago with a provision which was supported by the administration, and by the chairman of this committee, creating a semiautonomous status for the Cancer Institute within the NIH, I opposed it and voted against the bill for the reason that I thought it was deleterious to the National Institutes of Health and counterproductive from the standpoint of helping the cause in this major effort in the cancer field.

At that time every single medical organization and scientific organization in America that took a stand, took a stand against that provision for a semiautonomous status for the Cancer Institute. They included the Association of American Medical Colleges, the American Medical Association, the American Association for Cancer Research, the Federation of American Societies for Experimental Biology, and many more.

There was no medical organization that I know of and no scientific organization which was not critical of that provision.

Now, in this news story, in the Washington Post, Nov. 21, 1973, there is a comment by you, Dr. Edwards. Having been in politics a long time, I know that what the newspapers say may not always be correct, and only a couple of words in this article are actual quotes.

Anyway, the opening of the story says, "The Government's chief health official, Dr. Charles Edwards, said yesterday that Congress and the President made an administrative 'mistake' by giving the war on cancer semi-independent status in the Federal bureaucracy."

I would ask you to comment on that. If you believe that to be so, would you think we ought to have some kind of a review of the administrative procedures called for in the Cancer Act, and a recommendation to the Congress as to whether to continue that semi-independent status or to reestablish cancer's position with the same status as the other Institutes?

I understand, since the law has not been interpreted strictly, that you had more of an input and administratively kind of worked things out, so the bill did not quite accomplish what the strict language did say.

Would you like to comment on that, Dr. Edwards?

Dr. EDWARDS. Yes, Senator. I made that comment in response to a discussion that we were having regarding the National Institutes of Health.

Let me first say I think one of the great strengths in the entire health system in the United States is the National Institutes of Health and I think one of the reasons that it has this great strength is it is an organization that has in the past utilized interdisciplinary strengths, the Institutes working together.

There has been a program balance out there that I think has strengthened the organization. I think the Secretary has very adequately expressed our position.

We feel under Dr. Rauscher and Dr. Stone's leadership the current cancer program is working very well and the leadership has been excellent.

The thing that would concern me is that we do not split or give the other Institutes of the National Institutes of Health partial autonomy because in the final analysis what we would be doing would be destroying NIH and I think that is too vital a national resource to take any chance with its viability.

Senator NELSON. Well, the paper is correct. It quoted you as saying it was an administrative mistake.

Dr. EDWARDS. I think just from a poor management point of view it does add difficulties whenever you add different lines of authority, change the command and so forth, but nevertheless we have made it work and I think at the moment the important thing is to keep the program in place, keep the leadership which has demonstrated itself, in our judgment, very conclusively effective and not interfere with the progress that has been made and that is currently going on.

Senator NELSON. Well, if it is in your judgment an administrative mistake sufficient to comment on publicly, would you recommend there be some reevaluation of that aspect of that piece of legislation with recommendations, if the evaluation indicates there ought to be recommendations, for change?

Dr. EDWARDS. Well, I think we constantly have to reevaluate the way we are operating the Federal health establishment.

I think as the Secretary has said, I think there is, whether we admit it or not, a limit as to how much the public is willing to pay for biomedical research.

If that is true, we have to set up under the Director of the National Institutes of Health a priority, a system that will help us develop priorities; and I think that this has to be done by the Director of the National Institutes of Health, an individual who has access and information and the overall view of the biomedical research effort, not just the Federal Government and the Nation generally.

As a result of that I think we have to constantly reevaluate how we are doing business.

Senator NELSON. I had a previous engagement, so I could not be here, and if the questions have been asked, tell me so.

We constantly hear in reports in the press, and I hear from acquaintances and friends and others, in NIH, that the morale in the National Institutes is very low, and that you are losing lots of scientists.

I do not know whether I am correct in my memory about this, but I seem to recall 1,000 have left since 1968.

In any event, you continue to hear this, and I continue to talk to doctors who are associated on some of the advisory panels, and I talk to others in the Institutes, and it is repeated often enough so it is very disturbing to me to have people who have been there and are dedicated saying that the morale is very low, the lowest that they know of. I know some personally who have already left, and some others who are going to leave.

What is your evaluation of that assertion in the press about many of the employees out there?

Dr. EDWARDS. Are you speaking to me?

Senator NELSON. Well, whoever is knowledgeable.

Dr. EDWARDS. Well, I will speak to it, and then anyone else can speak to it, if they like.

The National Institutes of Health have had morale problems. There is no question about it.

I think over the past, under Doctor Stone's direction, however, I think this morale has been improving. I think the morale problems that have occurred in the past occurred for a number of reasons.

I think we have had them because there has been some tightness in the budget. I think there have been morale problems because there have been a number of people out there who believe very strongly in this balance of programs, who see the balance shifting in favor of two categorical programs; namely, cancer and heart disease.

I am not arguing whether this is right or wrong, but nevertheless it does create a morale problem for those in the other Institutes.

We have changed directors in the last year, and whenever you change a director of any organization, it creates a certain number of morale problems.

The deputy director is leaving. That has created a certain number of problems. That comes as no great shock. It was indicated that he was likely to leave a year ago.

These are all issues that I think Doctor Stone has under control, and I think under his leadership since July 1, there has been a definite improvement in morale in the general operation of the whole National Institutes.

Senator NELSON. I have no further questions.

Senator KENNEDY. Thank you very much, gentlemen.

We will submit some other questions to you in writing.

[The questions and answers referred to and other information supplied for the record follows:]

THE SECRETARY OF HEALTH, EDUCATION, AND WELFARE
WASHINGTON, D.C. 20201

Honorable Edward M. Kennedy
Chairman, Subcommittee on Health
Committee on Labor and Public Welfare
United States Senate
Washington, D. C. 20510

Dear Senator Kennedy:

This is in further response to your letter of February 6 requesting answers to several questions concerning S. 2893, the National Cancer Act Amendments, which we did not have the opportunity to cover in detail during my testimony before your Subcommittee. I submit the enclosed answers for your consideration.

If I can supply any additional information or be of any further service to you or your Subcommittee on this matter, please let me know.

Sincerely,

/s/ Caspar Weinberger

Secretary

Enclosure

COPY

Question #1

What were the position ceilings for NCI in fiscal years 1972, 1973 and 1974 and what is projected for fiscal year 1975? What were the NCI requests for positions for those years? How many supergrade positions does NCI now have and how many unfilled requests do they have? How are supergrade positions allocated to NCI from NIH?

Answer

Budgeted positions for NCI:

Fiscal Year 1972 -- 1,669
Fiscal Year 1973 -- 1,736
Fiscal Year 1974 -- 1,844
Fiscal Year 1975 -- 1,873

NCI Requests for Positions:

Request

Fiscal Year 1972 -- 1,680
Fiscal Year 1973 -- 1,935
Fiscal Year 1974 -- 2,138
Fiscal Year 1975 -- 2,088

NCI has 40 supergrade or their equivalent positions. Approximately 30 more supergrade or their equivalent positions have been requested. On an annual basis, NIH requests NCI to submit all their supergrade or equivalent needs to NIH in priority order. NIH reviews the need of NCI and all other Bureaus, Institutes, Divisions, and NIH makes a determination as to how many supergrades or their equivalent will be allocated to NCI.

Question #2

How many expert appointments have been made at the NCI under Section 410(1)? What are the terms of employment under this type of appointment and why has the NCAB asked to increase the number authorized from 50 to 100?

Answer

To date the NCI has appointed 14 experts under Section 410(1). Expert appointments under this authority receive all Civil Service benefits except tenure. Appointments under this authority can be extended for up to 4 years. Experts are paid within the supergrade salary ranges. The NCAB asked to increase the number authorized from 50 to 100 for two reasons: first, they viewed it as a way to increase NCI supergrade level personnel, on the assumption that these positions can be filled outside the Institute's personnel ceilings which is not the case, and second, to allow more flexibility to recruit top scientific and administrative staff.

Question #3

What has been the impact of the NCI not being an agency-level organizatio within DHEW? Specifically, what limitations have been placed on the NCI Director's contracting authority? Have personnel reductions been made in the NCI Public Affairs Office and does the Director continue to manage a full range of public affairs activities on behalf of the National Cancer Program? Also, to what grade level does the Director, NCI, have complete (i.e., without prior review and approval) authority to appoint and promote personnel in the NCI?

Answer

Currently, the NCI is a Bureau-level organization within NIH, which is an "agency" in the terms applicable to HEW organization. For most administrative purposes the Director, NCI, reports through the Director, NIH, the Assistant Secretary for Health, to the Secretary, DHEW. If the NCI were raised to an Agency level within the DHEW, the Director, NCI, would be organizatonally equal to the Director, NIH.

Administrative authorities are normally delegated from each higher level organization to succeeding lower levels. Consequently, except for authorities which are vested by law in the Director, NCI, the administration of the National Cancer Program is subject to delegations of authorities from levels noted above except for the budget authority of P.L. 92-218.

The Secretary, DHEW, has essentially delegated all research contracting authority to Agency heads, including the Director, NIH. The Director, NIH, in turn, has delegated all of these authorities to the NIH Bureaus, including NCI. The Secretary, and hence the Director, NIH, has retained only the authority to establish overall HEW procurement policies and procedures and to conduct pre-award review and approval of all contracts in excess of $500,000 and non-competitive contracts in excess of $100,000 and to appoint contracting officers.

The Office of Public Affairs for the National Cancer Institute and the National Cancer Program has been terminated, and the Institute's personnel positions were reduced by six as a result of the DHEW public affairs' reorganization.

The public affairs' activities of NCI and the national program are now being met by the central NIH Office of Public Information as are the needs of the other Institutes within NIH.

Question #3 (continued)

The Director of the National Cancer Institute goes through the NIH to have direct access to the mass media, though, of course, the mass media contact him directly. Audiovisual production resources together with certain other related technical services also are available to the NCI Director through NIH.

Moreover, as part of the public affairs reorganization, DHEW has set new regulations and rules for contracting for such services as printing (excluding GPO or internal printing of publications), graphics, audiovisuals, exhibitry, writing and editing. These new requirements include concept and other clearances by the Assistant Secretary for Public Affairs. They apply to contracts for public information and education and for information and education communications activities among NCI and practicing physicians, research scientists and hospitals, professional and voluntary groups, and other institutions and agencies participating in the cancer research effort.

The Director, NCI, or his designee has final authority for the appointment or promotion of any employee through Grade 14 and for GS-15 scientists in the extramural research area. Other personnel authority retained by the Director of NIH is as follows:

a) He must concur in appointments or promotions at Grade 14 for the top position in the function areas of executive and administrative management; financial mangement; personnel management; management analysis; grants or contracts administration; procurement; supply management; business data systems; program planning and evaluation; legislative analysis; resources analysis; and public information.

b) The NIH Director must concur in the appointment or promotion of any GS-13 through GS-15 professional, scientific or technical support positions in the intramural, collaborative, or other direct research programs. This includes personnel engaged in the scientific application of computer data systems.

c) The NIH Director must approve or clear the appointment or promotion of research assistants/technical positions above GS-9 in intramural, collaborative, or other direct research programs when filled by non-doctorate personnel.

Question #4

How were the authorization levels approved by the National Cancer Advisory Board and President's Cancer Panel derived?

Answer

In developing the five-year resource projections for the NCP Strategic Plan an analysis of alternative budget levels was conducted. The result of this analysis is presented in the document entitled "An Analysis of Mid-Range Resources Requirements for the National Cancer Program" dated March 1973, DHEW Publication No. (NIH) 74-571.

Three basic resource projection levels were developed: (1) an estimate which reflected an almost zero growth in the program; (2) an estimate which reflected an accelerated program taking maximum advantage of available knowledge and opportunities; and (3) an estimate whch falls between the other two levels. This last estimate was presented in the Strategic Plan.

These estimates take into account such factors as the resources needed to implement the recommendation of the Airlie planning sessions, resources committed to current research programs, categories and numbers of manpower needed to implement the program (and direct and indirect costs and resources associated with these categories of manpower), facilities, impact of inflation on salaries, supporting resources (e.g., materials, equipment) and construction, but they do not consider the balance of biomedicine research needs for other than cancer research

These estimates were presented to the National Cancer Advisory Board at the June 1973 meeting, and a subcommittee was appointed to review the material and make recommendations. This subcommittee's report at the Board's October meeting led to slight modifications in the curves presented in the "Mid-Range Analysis."

Question #5

Clarify the opening statement regarding how many comprehensive cancer centers would be needed to put various percentages of the U.S. population within approximately a 60-mile and 120-mile radius of these centers.

Answer

Population studies have been carried out to determine the potential impact of comprehensive cancer centers programs based on geographic distribution of proposed centers. Today, 53 million Americans are within 60 miles of a comprehensive cancer center, and 98 million Americans are within 120 miles. By July 1974, with the 15 centers authorized by law (and the three pre-existing), it is expected that six additional centers will be designated, bringing approximately 60 percent of the American population within daily commuting distance of a center.

The rationale in the opening statement was that providing centers within commuting distance of 60 percent of the U.S. population is optimal population coverage for a large demonstration program. We do not intend for the cancer research and demonstration centers to be a separate federally-built and funded health care system for cancer patients. The purpose of these centers is to demonstrate the most effective and the latest methods of cancer treatment. The 15 centers authorized by law will provide more than ample population coverage for these demonstration efforts. There would be little relative gain in expanding the number of centers. As the above figures indicate, we would have to double the number of centers to reach even 15 percent more population.

Question #6

How are comprehensive cancer centers designated?

Answer

The National Cancer Advisory Board together with NCI staff has established criteria for qualifications as a Comprehensive Cancer Center. Those institutions submitting applications for grant support of a comprehensive center undergo a peer review by outside consultants, with final review being made by the National Cancer Advisory Board. The results of the peer review, including evaluation for comprehensive criteria are communicated to the Director of the National Cancer Institute. Comprehensive centers are designated by the Director based on peer review and advice of the National Cancer Advisory Board.

Question #7

Explain the process by which research and other activities in a comprehensive center receive NCI grants and contracts.

Answer

Core grants (Cancer Center Support Grants) are for the purpose of funding centralized and coordinating functions of a cancer center including salaries and benefits of professional personnel, administration, planning and evaluation, development of new projects, certain hospitalization and clinical costs, alteration and renovation, equipment, supplies and community services. Research and other functions are funded through the normal funding mechanisms, e.g., individual research grants, fellowships, program project grants and contracts. All grants undergo competitive review, traditional research grants by the appropriate Division of Research Grants' Study Section and program project grants and core grants by the Cancer Special Program Advisory Committee or Cancer Research Center Review Committee. Contract support within comprehensive centers must meet the same requirements as any other NCI contract.

Comprehensive centers must augment their support of research by a multiplicity of sources since the core grant supports research only to the extent of providing "seed money" for developing new research project grant programs, after which investigators must obtain funding through normal grant or contract mechanisms.

Centers are encouraged to seek support from various Federal sources, State and local sources, charitable donations and patient care charges.

Question #8

What is the International Cancer Research Data Bank as it is presently being developed? Who will it serve; what are the problems being encountered and when will it be operational?

Answer

On the basis of advice from experts in information science, cancer scientists, and other advisors from various countries, the concept has evolved of a data bank program as an integrated and coordinated GROUP of activities that collect, process and disseminate information related to cancer. Its purpose is to facilitate and promote the exchange of cancer research information between research scientists and clinicians.

Many systems for dissemination of cancer related information already exist. For example, the processing of information related to chemotherapy and carcinogenesis is already well developed within the NCI. In addition many commercial services cover various aspects of the cancer literature. Under these circumstances, the primary effort of the ICRDB Program at this time is devoted to identifying specific gaps in the existing information services and developing products and services which will fill these gaps. At the same time the ICRDB Program is developing methods for gathering information data in specific cancer-related areas from diverse sources, bringing it together in central locations, and processing the data so that it is in a more useful form and more easily available to cancer researchers.

The initial phase of the ICRDB Program development included the following accomplishments (some still in progress):

1) Developed a set of recommendations for the ICRDB Program by a group of cancer researchers, information scientists, library scientists, and information systems managers (May 1972).

2) Arranged for an international advisory group (Committee on International Collaborative Activities (CICA) which is a component of the International Union Against Cancer (UICC) in Geneva) to review development of the ICRDB and provide advice on future efforts.

3) Selected a contractor and awarded a contract to Informatics, Inc. to design a comprehensive system for the ICRDB and to produce some of the specific products and services listed below. (Awarded in May 1973 at the $800,000 level.)

4) Produced a directory of cancer research institutions and cancer-related research projects to promote interaction between scientists working in similar areas.

5) Developed plans for a center which will collect, update, and disseminate information about current cancer research projects.

6) Developed plans for setting up a series of cancer information analysis centers, each of which will provide a spectrum of information products and services in a major area of cancer research. The major approach is to use present computer technology to keep each scientist and clinician aware of current research projects similar to his own, to call his attention to results of related projects as soon as they are released by other researchers and to permit rapid and efficient on-line searching and retrieval of cancer research results obtained in the past.

7) Conducted an extensive survey of cancer researchers and clinicians to determine their present patterns of information use and their need for new types of information products.

8) Began the comprehensive design for the ICRDB Program taking into account the results of the User Survey and the Survey of Existing Cancer Information Systems.

9) Began the preparation of magnetic tape data bases that will facilitate computer searching of cancer-related information.

10) Established how cancer-related data bases prepared by the ICRDB Program can be incorporated into the computer system at the National Library of Medicine and made available throughout the United States and abroad for searching on computer terminals linked to the National Library of Medicine system.

11) Supported development of a registry for collecting and disseminating information about clinical trials involving use of immunotherapy for treating cancer.

12) Began negotiations for use of the French SABIR cancer data base in the United States. This data base is derived from articles describing the results of nearly 25,000 cancer research projects.

13) Developed plans for a Clearinghouse which will collect and process information about current research on cancer epidemiology. This activity will be centered at the International Agency for Cancer Research in Lyon, France.

14) Prepared a catalog listing current information activities supported by NCI. This catalog describes NCI support of data centers which collect and process clinical information on cancer patients both in the United States and in Europe (The European Organization for Research on the Therapy of Cancer or EORTC), as well as support for the Environmental Chemical Information System which processes information about environmental agents that may cause cancer in man.

The ICRDB will facilitate and promote the exchange of information between researchers working on basic cancer biology and clinical cancer researchers. The ICRDB will interface directly with the first two groups of users. It will cooperate fully with and provide information to the Cancer Control Program which has the primary responsibility for interface between NCI and physicians who are treating cancer patients.

The technical, administrative, and political problems associated with the gathering, processing, and dissemination of information on an international scale are inherently quite complex, requiring extensive planning and the solution of many problems arising at each step in ICRDB development. These problems must be solved as ICRDB services are to be made available.

Some products and services have already been provided or are in various stages of planning (see Section A). Demonstration products and services which are used to evaluate and optimize the techniques will be the primary output of the ICRDB in 1974. This will include the availability of detailed cancer chemotherapy abstracts with in-depth indexing through the computer system of the National Library of Medicine by the second half of 1974.

Centers for collection, processing, and disseminating information in almost all major areas of cancer information (chemotherapy, carcinogenesis, cancer immunology, and cancer virology) should be in operation by mid-year 1975. Each of these centers will be engaged in actively promoting the exchange of cancer information and responding to requests in the assigned subject area within a few months after it is established. The data base, subject coverage, and information products and services of each center will grow as funds permit over the next few years.

As problems related to specific subject areas are solved by each center, an effort will be made, beginning in 1976, to increase the efficiency of the centers by combining and centralizing certain selected data gathering, processing, and disseminating activities.

Question #9

Please also submit the latest version of the report required by Section 4(a) regarding the review of all administrative processes under which the National Cancer Program is carried out.

Answer

This report is still in preparation. It will be forwarded to the Committee as soon as our analysis and review of these complex processes are completed.

HARRISON A. WILLIAMS, JR., N.J., CHAIRMAN
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ROBERT E. NAGLE, GENERAL COUNSEL

United States Senate
COMMITTEE ON
LABOR AND PUBLIC WELFARE
WASHINGTON, D.C. 20510

February 6, 1974

The Honorable Caspar Weinberger
Secretary
Department of Health, Education & Welfare
Washington, D.C.

Dear Mr. Secretary:

As I indicated to you at the conclusion of your testimony the other day on S. 2893, the National Cancer Act Amendments of 1974, I would very much appreciate the Department's response to the following questions which we did not have a chance to go into detail on during the hearing:

1. What were the position ceilings for NCI in fiscal years 1972, 1973 and 1974 and what is projected for fiscal year 1975? What were the NCI requests for positions for those years? How many supergrade positions does NCI now have and how many unfilled requests do they have? How are supergrade positions allocated to NCI from NIH?

2. How many expert appointments have been made at the NCI under Section 410(1)? What are the terms of employment under this type of appointment and why has the NCAB asked to increase the number authorized from 50 to 100?

3. What has been the impact of the NCI not being an agency level organization within DHEW? Specifically, what limitations have been placed on the NCI Director's contracting authority? Have personnel reductions been made in the NCI Public Affairs Office and does the Director continue to manage a full range of public affairs activities on behalf of the National Cancer Program? Also, to what grade level does the Director, NCI, have complete (i.e., without prior review and approval) authority to appoint and promote personnel in the NCI?

4. How were the authorization levels approved by the National Cancer Advisory Board and President's Cancer Panel derived?

5. Clarify the opening statement regarding how many comprehensive cancer centers would be needed to put various percentages of the U.S. population within approximately a 60-mile and 120-mile radius of these centers.

6. How are comprehensive cancer centers designated?

7. Explain the process by which research and other activities in a comprehensive center receive NCI grants and contracts?

8. What is the International Cancer Research Data Bank as it is presently being developed? Who will it serve; what are the problems being encountered and when will it be operational?

9. Please also submit the latest version of the report required by Section 4(a) regarding the review of all administrative processes under which the National Cancer Program is carried out.

It is my intention to expedite the enactment of S. 2893. Therefore, I would very much appreciate a prompt reply to this request.

Sincerely,

Ted Kennedy

Edward M. Kennedy, Chairman
Senate Health Subcommittee

HARRISON A. WILLIAMS, JR., N.J., CHAIRMAN

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CHIEF LEGISLATIVE COUNSEL
MARJORIE M. WHITTAKER, CHIEF CLERK

United States Senate
COMMITTEE ON
LABOR AND PUBLIC WELFARE
WASHINGTON, D.C. 20510

September 30, 1974

The Honorable Edward M. Kennedy
Chairman
Senate Health Subcommittee
Washington, D. C.

Dear Senator Kennedy:

On February 4, 1974, we requested specific information from the Department of Health, Education, and Welfare regarding implementation of the National Cancer Act of 1971. On September 23, 1974, we received answers to our queries.

It would be appreciated if the February 4 letter and the September 23 responses were printed as part of the hearing record on the National Cancer Act Amendments of 1974.

In addition, enclosed is the Zinder Report on the Special Virus Cancer Program, with appendices, and articles about the National Cancer Program, which I would appreciate having inserted into the hearing record.

Sincerely yours,

Gaylord Nelson

GAYLORD NELSON
U. S. Senator

GN:cwr

HARRISON A. WILLIAMS, JR., N.J., CHAIRMAN
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United States Senate
COMMITTEE ON
LABOR AND PUBLIC WELFARE
WASHINGTON, D.C. 20510

The Honorable Caspar Weinberger
Secretary
Department of Health, Education & Welfare
330 Independence Avenue, S.W.
Washington, D.C.

Dear Mr. Secretary:

Three years after the enactment of the special cancer program law, we are now concerned with examining the impact the law has had.

With such a large influx of Federal money, it is important that the program is serving the public health in the best possible way.

It is a matter of public knowledge that there has been some unhappiness, both within HEW and the scientific community at large, about the way the Cancer Act was structured and implemented.

Dr. Edwards, on November 20, 1974, called the administrative and budget arrangement in the cancer program a "mistake," and indicated that budgetary favortisim for cancer research might be at the expense of other research programs.

Morale at the National Institutes of Health is reported to be very low, and a number of scientists are leaving the service of the Federal Government.

There should be a careful review of the impact the Act has had and the way it is being implemented, so that further erosion of the NIH constituency is halted, and the excellent biomedical research that NIH fosters goes forward.

The public should have confidence that its tax dollars are supporting the best possible research in the world in the most productive and efficient way possible.

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A number of questions have arisen about the cancer program, which I would like to have answered for the hearing record, beyond those that were discussed during the oral hearing. I have asked that your responses, along with this letter, be inserted into the hearing record.

Spending for cancer research jumped from $180 million for the National Cancer Institute budget in 1971 to $432 million in 1973, and $551 million in 1974. Outside of the National Heart and Lung Institute budget, which also increased, the nine other Institutes at NIH suffered budget cuts in these years.

Dr. Marston, in an October 6, 1972 memo to the HEW Assistant Secretary for Health and Scientific Affairs, decrying proposed cuts in the 1974 NIH budget, expressed great concern over large increases for cancer research without adequate funding for other research areas.

> *"Such a budget would belie any assertion that cancer research growth was not at the expense of other research. More importantly from a substantive standpoint, it might well undercut the promise of significant progress in cancer research itself.* For instance, the two most promising areas of cancer research today are immunology, including the studies on BCG, and the area of viral oncology. These areas originally were developed and supported to the point of potential benefit in cancer research by the programs of the National Institute of Allergy and Infectious Diseases. The comparison in funding between these two Institutes fails completely to reflect the heavy dependence of future cancer research on the continued development of more general knowledge in fields such as these, as well as fields represented in other Institutes.
>
> "In summary, we support the cancer proposal but must express concern at a budget that increases cancer by $208 million, heart by $23 million and the balance of biomedical research by $28 million. *Additionally, we are also seriously concerned with the capability of the NIH to provide service and logistical support for such an effort without a commitment in 1974 and future years for central staff and facilities.*" (Emphasis Added.)

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James D. Watson, Nobel Prize winner, professor at Harvard University and Director of the Cold Spring Harbor, New York, Laboratory, had this to say in testimony before the House Subcommittee on Public Health and Environment, March 20, 1973:

> "We thus must not be falsely reassured by the recent federal budget which announces an increase in money for cancer research. While the NCI component does go up, it is only at the expense of other branches of the NIH, any one of which might be the funding body for the scientist(s) who stumbled onto the essential facts we all want.
>
> "Moreover, in looking over the research programs now supported by NCI, comparing them to projects assigned to pigeon holes in other institutes, I am constantly struck by the fact that the vast majority of the best American Biologists are not now supported by NCI but all too often by the Institute for General Medical Sciences, a body without friends on the top and whose budget assignments are increasingly meager."

Moreover, although the NCI staff positions have been allowed to increase since 1968 by about 350 positions, a hold-down on personnel positions has been effected by HEW over the rest of the Institutes,so that, since 1968, it is my understanding that all other Institutes have had a total loss of about 1,000 staff personnel, who have not been replaced.

1. What have been the number of fulltime permanent positions at each Institute, including the Cancer Institute, in each year from 1968 to the present?

   Are these positions largely scientific and professional staff?

2. You testified before the Senate Health Subcommittee that the increases in budget allocations for cancer research had not been made at the expense of other research programs supported by NIH, and that for fiscal 1975, additional funds for cancer research would not be taken from the other Institutes.

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Nevertheless, the proposed 1975 budget shows that the cancer research budget would increase by $73 million to a total of $600 million; that the heart and lung research budget would increase by $23 million to a total of $309 million; but that all other Institute budgets together would increase by only $457,000, and that the Research Resources budget, which I understand is used to support grants for basic research, would drop by $44 million.

If I have these figures correct, it would appear that other Institute budgets are suffering. Please give me your views on this.

Please include figures showing the total budget authority and allocations for each Institute, including the Cancer Institute, from 1970 to fiscal 1975.

3. Who actually is directing the program? The NCI Director? The NIH Director? The Secretary of HEW? The President's Cancer Panel? OMB? Or the President?

   For example, who selects members of ad hoc advisory committees, which the Act says may be established?

4. Do you believe it would be wise to make the NIH Director less tied to political appointment, by setting a time limit on his appointment, and having it confirmed by the Senate?

5. An NIH Committee, the Program Mechanisms Committee headed by Dr. Theodore Cooper, Director, National Heart and Lung Institute, made a study of the NIH contracting process, and in February of last year (1973), recommended that NIH adopt uniform policies and procedures for selecting both grants or contracts, to avoid conflict of interest in contract awards, and to expand to contracts the same kind of peer review system now applied for grants.

   Have these recommendations been implemented for the research and development contract procedure?

   Do you favor a form of peer review by outside experts for both contracts and grants?

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6. The National Cancer Advisory Board became concerned last year that the cancer grant program supporting "basic", investigator-initiated research was being down-graded in favor of NCI-directed, contracts for "targeted" research.

   The Advisory Board voted almost unanimously to urge that no less than 50% of the available cancer money go to grants.

   What is the percentage of grants versus contract awards now? What was the percentage in 1970, through 1973? What is your view of this matter?

7. It is our understanding that some $237 million has been spent on the Special Virus Cancer Program since it began in 1965, entirely on contracts and intramural research. The National Cancer Advisory Board named a special ad hoc committee to review the virus program.

   What were the committee's recommendations, and what is the status of that program now?

8. In August 1973, an ad hoc NIH "Committee on Testing for Environmental Chemical Carcinogens" issued a report, recommending that more special attention be focused on this aspect of cancer research, and that a Federal Council on Environmental Carcinogenic Hazards be established, analogous to the Federal Radiation Council, which formulated Radiation Protection Standards.

   Have the recommendations of this Committee been implemented?

9. What percentage of cancer money is going to Chemotherapy Research? Immunology Research? Virology Research? Hemotology Research? Other research areas? (Identify.)

10. We understand that platelet therapy has some potential for cancer research, as well as for aplastic anemia.

    Is NCI funding such research, and how does the funding compare to that for such research in past years?

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11. Are there enough adequately trained researchers to carry out the potential expanded research in cancer? Do we need to support training of more researchers?

12. Should federal support continue for pre-doctoral research training, as well as for post-doctoral training?

13. In a January 24, 1974, letter to the Washington Post, responding to an editorial, which, in turn, discussed Dr. John Sherman's resignation as Deputy Director of NIH, Dr. Edwards made reference to NIH leadership not having been "more perceptive and responsive" so as to prevent the "removal of the cancer research effort from the administrative control of NIH, a move that threatens the further dissolution of biomedical research efforts."

    Quite clearly, the leadership at NIH opposed creating a special status for cancer at the time the Congress was debating the Cancer Act. The HEW Department and the White House changed positions several times, from supporting a separate cancer status to opposing it, to supporting a modified semi-independent status.

    In what way should the NIH leadership, which consistently opposed an independent cancer research effort, have acted differently?

Thank you for your cooperation in answering these questions for the record.

Sincerely,

GAYLORD NELSON
U.S. Senator

GN/jrl

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THE SECRETARY OF HEALTH, EDUCATION, AND WELFARE
WASHINGTON, D. C. 20201

Honorable Gaylord Nelson
United States Senate
Washington, D. C. 20510

Dear Senator Nelson:

This is in response to your questions concerning S. 2893, the National Cancer Act Amendments, which we did not have the opportunity to cover in detail during my testimony at the hearing. We regret the delay in responding to your concerns.

Enclosed are the responses to the specific questions you raised. We would, in addition, like to address some of the broader issues which you raised in connection with these questions.

On the issue of "budgetary favoritism" for cancer research, we noted at the cancer hearing that we believe that we have balanced programs among the Institutes at the National Institutes of Health. Furthermore, it is our belief that the structure of the current cancer program is working well, and that the program has excellent leadership. It is, nonetheless, the Department's concern that other NIH institutes not be given special semi-independent status as was done with the cancer program. This, we feel, would ultimately destroy the Institutes' interdisciplinary strengths, and thus their viability. Moreover, it would be contrary to the agreed upon priority of cancer research.

With regard to your views on the expansion of the cancer program in relation to other Institutes, I should note that the growth rate of the other Institutes had previously been in excess of 25 percent each year for many years. It is inevitable that this trend would eventually end. This does not mean that the program of the other institutes has been disrupted or that the quality of their research reduced. It simply means that Federal funds are not available to continue to increase all programs at the same time.

In connection with your concern about low morale at NIH, there may have been some truth to that allegation when the National Institutes of Health was without a director for a period of time last year. However, it is our observation that since July of 1973 morale has improved considerably.

With respect to turnover rates, we believe that the failure of Congress to enact higher salaries for our scientists at the super grade levels as requested by the President is much more a cause of scientists leaving the Federal Government than "low morale." We believe that enactment of the Administration's proposals in this area--along with implementation of the new physician bonus authorities for the Public Health Service Commissioned Corps--will contribute to retention rates.

Your letter also expressed general concern about the future direction of biomedical research at NIH. I am confident that the Assistant Secretary for Health, along with the NIH Director and his scientific staff, can work together successfully to exert the necessary leadership for Federally-supported biomedical research.

In addition, Section 201 of the National Cancer Act Amendments of 1974, P.L. 93-352, establishes the President's Biomedical Research Panel to identify and make recommendations with respect to policy issues concerning the organization and operation of biomedical and behavioral research conducted and supported under programs of NIH and NIMH. We also welcome the opportunity to assist this Panel in any way possible in our common goal of furthering the quality of biomedical research.

Sincerely,

Secretary

Enclosures

Question #1

What have been the number of fulltime permanent positions at each Institute, including the Cancer Institute, in each year from 1968 to the present?

Are these positions largely scientific and professional staff?

Answer

Approximately one-third of the positions at the NIH are filled by professional and scientific personnel. See attached chart of comparable positions, FY 1968 - 1975.

## DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
## NATIONAL INSTITUTES OF HEALTH

### COMPARABLE END-OF-YEAR FULL TIME PERMANENT EMPLOYMENT
### FY 1968 - 1975 1/

| | 1968 | 1969 | 1970 | 1971 | 1972 | 1973 | 1974 Est. Original | 1974 2/ | President's Budget 1975 3/ |
|---|---|---|---|---|---|---|---|---|---|
| NCI............ | 1,453 | 1,411 | 1,355 | 1,426 | 1,663 | 1,720 | 1,820 | 1,820 | 1,855 |
| NHLI........... | 609 | 564 | 558 | 584 | 618 | 641 | 656 | 687 | 656 |
| NIDR........... | 301 | 291 | 283 | 289 | 288 | 287 | 265 | 267 | 265 |
| NIAMDD......... | 633 | 615 | 588 | 597 | 585 | 579 | 551 | 560 | 551 |
| NINDS.......... | 732 | 652 | 588 | 583 | 557 | 527 | 515 | 524 | 515 |
| NIAID.......... | 706 | 695 | 676 | 665 | 623 | 604 | 590 | 599 | 590 |
| NIGMS.......... | 207 | 191 | 180 | 164 | 167 | 147 | 153 | 153 | 153 |
| NICHD.......... | 405 | 400 | 415 | 435 | 482 | 510 | 514 | 523 | 524 |
| NEI............ | -- | 59 | 85 | 92 | 117 | 121 | 127 | 132 | 127 |
| NIEHS.......... | 169 | 176 | 202 | 220 | 235 | 228 | 233 | 235 | 233 |
| RR............. | 98 | 85 | 82 | 83 | 78 | 75 | 71 | 71 | 71 |
| FIC............ | 62 | 46 | 48 | 47 | 59 | 53 | 49 | 49 | 49 |
| TOTAL IRD'S.. | 5,375 | 5,185 | 5,060 | 5,185 | 5,474 | 5,492 | 5,544 | 5,620 | 5,519 |
| NIM........... | 491 | 489 | 461 | 462 | 465 | 456 | 455 | 465 | 455 |
| OD............ | -- | 472 | 473 | 489 | 490 | 513 | 525 | 531 | 525 |
| MF............ | 4,389 | 3,527 | 3,403 | 3,470 | 3,330 | 3,326 | 3,265 | 3,373 | 3,284 |
| S&S........... | 676 | 779 | 736 | 645 | 624 | 701 | 606 | 606 | 606 |
| TOTAL, NIH | 10,931 | 10,452 | 10,133 | 10,251 | 10,383 | 10,488 | 10,395 | 10,595 | 10,459 |

---

1/ All years prior to 1975 adjusted to reflect organizational changes in NIH inherent in 1975 Budget

2/ Tentative, pending review by Director, NIH with each Institute Director.

3/ 1975 employment is currently being studied. Final decisions regarding a potential increase in employment ceiling have not been made.

Question #2

You testified before the Senate Health Subcommittee that the changes in budget allocations for cancer research had not been made at the expense of other research programs supported by NIH, and that for fiscal 1975, additional funds for cancer research would not be taken from the other Institutes.

Nevertheless, the proposed 1975 budget shows that the cancer research budget would increase by $73 million to a total of $600 million; that the heart and lung research budget would increase by $23 million to a total of $309 million; but that all other Institute budgets together would increase by only $457,000, and that the Research Resources budget, which I understand is used to support grants for basic research, would drop by $44 million.

If I have these figures correct, it would appear that other Institute budgets are suffering. Please give me your views on this.

Please include figures showing the total budget authority and allocations for each Institute, including the Cancer Institute, from 1970 to fiscal 1975.

Answer

The FY 1975 budget request for the NIH is $1,834,784,000, an increase of about $54 million from the amounts appropriated for FY 1974. This is made up, as stated in the question, primarily of increases in the cancer and heart/lung programs. These two programs have grown rapidly in line with their status as priority Presidential programs. Other biomedical research areas have grown, but less rapidly than the cancer or heart/lung programs. For example, the figures on the following page indicate that the budgets of the research institutes other than cancer and heart/lung increased by over $200 million in the 1970-1975 time frame. In short, the research budgets of the other Institutes have not been ignored.

It is true that the Research Resources budget is reduced by $44 million in 1975. This reflects the proposed phase-out of the General Research Support Grant Program (GRSC). The original objectives of this program have been met--high quality biomedical institutional strength has been built up. Now, it is believed, biomedical research funds will be more efficiently utilized in the regular research grant programs of the Institutes. Unlike GRSG funds, which are made available on a formula basis and for which no specific investigator initiated research is undertaken, research grant requests are subjected to a rigorous scientific review process which ensures that the best research projects proposed are funded. Minority Schools Biomedical Support Program (MSBS), however, a component of GRSC, will be continued in 1975 at its $7 million level. This program provides support to minority insitutions for the development of biomedical research activities.

A table showing comparable appropriations from FY 1970 to present is attached.

## NATIONAL INSTITUTES OF HEALTH

### COMPARABLE BUDGET AUTHORITY FY 1970 - FY 1975
### (IN THOUSANDS OF DOLLARS)

| | 1970 | 1971 | 1972 | 1973 | 1974 | Bud. Est. 1975 |
|---|---|---|---|---|---|---|
| NCI | $171,822 | $223,633 | $372,838 | $485,230 | $527,399 | $600,000 |
| NHLI | 148,451 | 182,360 | 224,389 | 287,927 | 286,749 | 309,299 |
| NIDR | 27,066 | 33,504 | 42,366 | 45,793 | 43,955 | 43,959 |
| NIAMDD | 125,122 | 125,095 | 145,032 | 158,257 | 153,736 | 152,961 |
| NINDS | 90,242 | 93,647 | 111,557 | 124,469 | 121,393 | 119,958 |
| NIAID | 91,265 | 92,329 | 103,986 | 107,698 | 111,146 | 110,404 |
| NIGMS | 139,197 | 146,557 | 166,358 | 173,757 | 166,805 | 168,329 |
| NICHD | 71,303 | 89,222 | 112,515 | 126,002 | 125,508 | 124,897 |
| NEI | 22,636 | 28,619 | 35,555 | 36,843 | 41,228 | 39,947 |
| NIEHS | 16,942 | 19,361 | 25,889 | 30,305 | 28,338 | 28,684 |
| DRR | 123,323 | 127,149 | 130,211 | 135,785 | 128,059 | 82,700 |
| FIC | 2,857 | 3,732 | 4,357 | 4,644 | 4,762 | 4,784 |
| Total, Research | 1,030,226 | 1,165,208 | 1,475,053 | 1,716,710 | 1,739,070 | 1,785,922 |
| NLM | 19,253 | 21,430 | 24,111 | 28,413 | 26,254 | 27,738 |
| B&F | 1,615 | --- | 3,565 | 8,500 | 8,000 | 3,000 |
| OD | 10,113 | 11,074 | 11,117 | 12,785 | 12,993 | 18,124 |
| TOTAL, NIH BUDGET AUTHORITY | 1,061,207 | 1,197,712 | 1,513,846 | 1,766,408 | 1,786,325 | 1,834,784 |

Question #3

Who actually is directing the program? The NCI Director? The NIH Director? The Secretary of HEW? The President's Cancer Panel? OMB? Or the President?

For example, who selects members of ad hoc advisory committees, which the Act says may be established?

Answer

The direction of the National Cancer Program is the responsibility of the Director, National Cancer Institute. The NCI is part of the National Institutes of Health within the Department of Health, Education, and Welfare, with special authorities given to the Director, NCI, by the Cancer Act of 1971. Under the Act, NCI's regular budget proposals are transmitted directly to the President. The Director, NIH, and Secretary, HEW, may comment, but not change the NCI budget requests. The policy and program decisions of the Director, NCI, are also rendered in concert with and based on evaluation of advice and counsel received from the National Cancer Advisory Board, special technical advisory committees composed primarily of nongovernment scientists, and senior Institute staff members. Policy and program decisions involving legal and administrative procedures are responsive to regulations promulgated by the Department of HEW and the Office of Management and Budget. The President has a special interest in the National Cancer Program and is kept apprised of the operations of the Program through the President's Cancer Panel.

Nominees for membership on ad hoc advisory committees are proposed by the Federal officials organizing the special groups, in this case administrators of the NCI. Appointment is contingent upon approval by program superiors and ultimately the Director, NCI. In addition, committee members are subject to approval in terms of NIH and Departmental guidelines regarding geographic representation, multiple committee membership, institutional representation, etc. Similar approval mechanisms exists for selection of members of standing committees.

Question #4

Do you believe it would be wise to make the NIH Director less tied to political appointment, by setting a time limit on his appointment, and having it confirmed by the Senate?

Answer

The National Cancer Act of 1972 made the positions of the NIH Director and the NCI Director Presidential appointments.

The position of the Director, NIH, should be filled by a competent scientist-administrator experienced in biomedical research. It has traditionally been filled by a Federal employee as a permanent career appointment. The characteristics considered essential to the position are scientific and administrative competence. We believe that the current methods of selection and appointment have satisfactorily addressed these important considerations. The proposal to make the NIH Director's appointment for a fixed term would not be in the best interests of effective management of the Department although the Department does not object to Senate confirmation of the NIH Director.

Question #5(a)

An NIH Committee, the Program Mechanisms Committee headed by Dr. Theodore Cooper, Director, National Heart and Lung Institute, made a study of the NIH contracting process, and in February of last year (1973), recommended that NIH adopt uniform policies and procedures for selecting both grants or contracts, to avoid conflict of interest in contract awards, and to expand to contracts the same kind of peer review system now applied for grants.

Have these recommendations been implemented for the research and development contract procedure?

Answer

The recommendations of the Program Mechanisms Committee have been accepted in principle and implementation is proceeding. The recommendations are very far reaching and implementation requires careful formulation, broad discussion, considerable examination of proposal details and perhaps even adoption by stages, based on preliminary trials of proposed procedures. The NIH is moving systematically toward putting them into effect and the Department's operational planning system is tracking progress.

Question #5(b)

Do you favor a form of peer review by outside experts for both contracts and grants?

Answer

Circumstances for peer review for research and development contracts are complex. In many cases, particularly those involving considerable innovative activity, technical merit review by scientific peers is completely appropriate and is currently employed by the NIH. In other instances where the nature of the project or problem comes close to resembling normal procurement activity, review by outside experts is not necessary. It would in fact be wasting the time of experts to review such routine activities since scientific content is not an important aspect of the project.

A substantial portion of senior NIH staff have been working for the last year to try to define more clearly the different circumstances which should and should not require peer review for various kinds of R&D projects. In view of the complexity of the system and the probable need for frequent adjustments, it would be unwise to establish such a system by statute.

Question #6

The National Cancer Advisory Board became concerned last year that the cancer grant program supporting "basic," investigator-initiated research was being downgraded in favor of NCI-directed, contracts for "targeted" research.

The Advisory Board voted almost unanimously to urge that no less than 50% of the available cancer money go to grants.

What is the percentage of grants versus contract awards now? What was the percentage in 1970, through 1973? What is your view on this matter?

Answer

The following percentages reflect the relationship between total research grant dollars and total research contract dollars spent by NCI between 1970 and 1975.

| Fiscal Year | Grants | Contracts |
|---|---|---|
| 1970 | 59.9% | 40.1% |
| 1971 | 54.9% | 45.1% |
| 1972 | 50.8% | 49.2% |
| 1973 | 54.0% | 46.0% |
| 1974 estimated | 55.3% | 44.7% |
| 1975 estimated | 57.4% | 42.6% |

It is NCI policy to strike a balance between the grant and contract mechanism. Grants are utilized to fund investigator-initiated projects while contracts are used to fund more highly targeted areas of research sometimes developed independently of the NCI and sometimes by NCI program leaders.

Question #7

It is our understanding that some $237 million has been spent on the Special Virus Cancer Program since it began in 1965, entirely on contracts and intramural research. The National Cancer Advisory Board named a special ad hoc committee to review the virus program.

What were the committee's recommendations, and what is the status of that program now?

Answer

The ad hoc Committee to review and evaluate the Special Virus Cancer Program of the National Cancer Institute submitted its final report to the National Cancer Advisory Board on March 19, 1974.

A copy of the report is attached. (See Zinder Report, II.3.I.)

Question #8

In August 1973, an ad hoc NIH "Committee on Testing for Environmental Chemical Carcinogens" issued a report recommending that more special attention be focused on this aspect of cancer research, and that a Federal Council on Environmental Carcinogenic Hazards be established, analogous to the Federal Radiation Council, which formulated Radiation Protection Standards.

Have the recommendations of this Committee been implemented?

Answer

The report of the ad hoc "Committee on Testing for Environmental Chemical Carcinogens" was submitted to the Director, National Cancer Institute on August 31, 1973. The recommendation to establish a Federal Council on Environmental Carcinogenic Hazards was considered and deferred pending organization of the DHEW Committee to Coordinate Toxicology and Related Programs, under the auspices of the Office of the Assistant Secretary for Health, DHEW. The latter Committee was organized and is chaired by the Director of the National Institute of Environmental Health Sciences, one of the NIH Institutes. The NCI is represented on that Committee by the Director, Division of Cancer Cause and Prevention. Consequently, and after consultation with Departmental, academic and staff representatives, the proposed Federal Council was considered duplicative and unnecessary. However, other recommendations of the Committee on Testing for Environmental Chemical Carcinogens, including the development of a national program for identification of chemical carcinogens and organization of an NCI Office of Interagency Carcinogenesis, have been implemented.

Question #9

What percentage of cancer money is going to Chemotherapy Research? Immunology Research? Virology Research? Hematology Research? Other research areas? (Identify.)

Answer

The NCI has a number of programs upon which special emphasis is placed. These programs represent areas of cancer research of significance due to the magnitude of the problems they address and/or the degree of progress being made in the area.

| Program | Percentage of FY 1973 NCI Funds |
|---|---|
| Chemotherapy Research | 16.4 |
| Virus Cancer Research | 15.0 |
| Chemical Carcinogenesis Research | 13.2 |
| Immunology Research | 5.3 |
| Organ Site Task Forces | 3.5 |
| Other Research Areas | 27.9 |
| Resource Development (non-research) | 18.7 |

Hematology research is not listed since it is not broken out as a separate entity by NCI programs and is not an area of special emphasis, except as it relates to the above listed areas.

Resource Development includes funding for Control Programs, Construction, Centers, Manpower, and Administration.

Question #10

We understand that platelet therapy has some potential for cancer research, as well as for aplastic anemia.

Is NCI funding such research, and how does the funding compare to that for such research in past years?

Answer

Platelet transfusions have become standard therapy for cancer patients whose ability to make platelets has been compromised by their disease, by radiotherapy or by chemotherapy. For over a decade NCI has been funding research for this important form of supportive therapy at an increasing level.

In this area of research, grant and collaborative funding has totalled as follows:

| Fiscal Year | Grants | Collaborative (contracts and in-house) | Total |
|---|---|---|---|
| | | (in millions) | |
| 1971 | $1.265 | $ .815 | $2.080 |
| 1972 | 1.454 | 1.044 | 2.498 |
| 1973 | 1.785 | 1.223 | 3.008 |
| 1974 estimated | 1.915 | 1.427 | 3.342 |
| 1975 estimated | 2.090 | 1.535 | 3.625 |

Question #11

Are there enough adequately trained researchers to carry out the potential expanded research in cancer? Do we need to support training of more researchers?

Answer

Currently, there are more than enough trained researchers to carry out the expanded cancer research effort.

The National Cancer Institute is presently conducting an analysis of the resources, including manpower, needed to implement the National Cancer Program Plan through fiscal year 1982. Two hundred fifty representatives of the cancer research community recently considered this issue at special planning sessions. Estimated levels of scientific manpower and distribution of scientists in Ph. D., M.D., and D.V.M. categories were developed for fiscal year 1972 based upon a stratified sampling of grants, contracts, in-house projects, and nongovernment institutions conducting cancer research activities.

This analysis indicated that roughly 10,500 scientists were involved in cancer research activities in fiscal year 1972. For fiscal year 1982, the National Cancer Program Plan projects estimated that a total of 28,400 scientific personnel would be needed to support the total range of cancer activities included in the plan. These estimates are based upon projected program levels in the National Cancer Program Plan and do not reflect any commitment for future funding levels.

The National Cancer Insitutes assists in the training of scientific personnel. The 1973 level of funding was $14 million; in 1974 the level increased to $22 million; and the 1975 requested appropriation maintains that $22 million level.

The Administration's new postdoctoral fellowship program will provide for necessary advanced training in research, not only in cancer but in other specified shortage areas in biomedical and health-related sciences. Approximately $30 million will be available this fiscal year (and $60 million next fiscal year) for two types of awards: (1) the Postdoctoral Research Fellowship to individuals which will provide a yearly $10,000 stipend to the recipient and up to $3,000 to the institution at which each fellow trains; and (2) a small number of Institional Research Fellowship Awards to be made to institutions for the support of individuals at the postdoctoral level.

The new fellowship program was adopted because the fellowships can be allocated to specific biomedical research areas where there are critical manpower shortages and demonstrated national need. Because of the availability increased amounts of general student assistance

Answer #11 (continued)

such as loan guarantee programs of the Office of Education, postdoctoral students can be expected to bear the costs of their own training. At the same time, postdoctoral students in areas in which there are manpower shortages will receive Federal aid under the new fellowship program.

Question #12

Should Federal support continue for predoctoral research training, as well as for postdoctoral training?

Answer

It is our view that as the old style NIH training grants, including those which supported predoctoral research training, should be phased out over the next several years, career incentives will continue to provide adequate numbers of predoctoral graduate students in the biomedical sciences. If there are realistic indications the Department will look into alternative ways to prevent any such serious shortages. We are, of course, monitoring the biomedical research manpower situation very carefully and there have been no indications to date of detrimental changes.

Question #13

In a January 24, 1974, letter to the Washington Post, responding to an editorial, which, in turn, discussed Dr. John Sherman's resignation as Deputy Director of NIH, Dr. Edwards made reference to NIH leadership not having been "more perceptive and responsive" so as to prevent the "removal of the cancer research effort from the administrative control of NIH, a move that threatens the further dissolution of biomedical research efforts."

Quite clearly, the leadership at NIH opposed creating a special status for cancer at the time the Congress was debating the Cancer Act. The HEW Department and the White House changed positions several times, from supporting a separate cancer status to opposing it, to supporting a modified semi-independent status.

In what way should the NIH leadership, which consistently opposed an independent cancer research effort, have acted differently?

Answer

It is true that the NIH leadership consistently opposed an independent cancer research effort. It did so in good faith on its implicit judgments of the impact of "separatism" of the National Cancer Institute from the remainder of the NIH. Perhaps had the leadership at NIH converted its implicit judgment to more explicit explanations of the scientific basis for the judgment it could have been more effective. Perhaps a formal written critique of potential consequences on the dissolution of the national biomedical research effort could have been more persuasive to those segments proposing the various organizational relationships between the NCI and the NIH. On the other hand, there were many advocates in the Congress and from among various sectors of the scientific community who were arguing forcefully that an expanded cancer research effort, to be successful, needed an organizational arrangement different from what was in existence at the time.

## ZINDER REPORT

On March 5, 1973 Dr. Frank Rauscher, Jr. at the request of the National Cancer Board appointed this ad hoc committee to conduct a review of the Special Virus Cancer Program of the National Cancer Institute and deliver a report of its findings and recommendations for the future. This document is our report. It represents the sum of our deliberations to date. We are willing to continue our review, should the Board desire additional information or analysis.

Since the SVCP represents one of the largest contract programs in the NIH, amounting to some 12% of the annual NCI budget, and thus might be considered the paradigm for such programs, we have interpreted the term "review" in the broadest of contexts. We have therefore attempted to analyze as far as possible, in the limited time available, all aspects of this program except those at the Detrick Cancer Center.

### COMMITTEE

Dr. Norton Zinder (Chairman)
Dr. James Darnell
Dr. Vittorio Defendi
Dr. Robert Good
Dr. Keith Porter
Dr. James Price
Dr. Wallace P. Rowe
Dr. Aaron Shatkin
Dr. Chandler Stetson
Dr. Richard Tjalma*

Dr. Maurice Guss (Executive Secretary, NCI)

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*Resigned due to appointment to the NCI

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## REVIEW PROCEDURES

Meetings

1. Organization
2. With Segment Chairmen and Program Management Segment
3. Attendance at one Segment Chairman's Meeting
4. Attendance at one Segment Committee meeting, the Solid Tumor Virus Working Group
5. With members of the working committees - overlaps with some contractors so dual in purpose
6. Attendance at Pacific Coast Meeting of Solid Tumor Virus Segment
7. Site Visits
    a) Flow Labs Contract 33247
    b) Litton-Bionetics, Bethesda, Md. Contract 73-3230
    c) University of Southern California, Contract 63-1030
8. Discussion of analysis of large contracts, results of our survey and our report

Documents

1. Two years of summaries of annual reports
2. One semi-annual report
3. Questionnaire to the users of resources and services as to quality and need
    a) Comments on program occasionally included in the responses
4. All (36) current contracts that are funded at

$300,000 or more per annum were reviewed. Each committee member reviewed four contracts, distributed as far as was possible on the basis of their individual area of expertise. The total sum represented by these contracts was over $32,000,000; a major portion of the program.

## INTRODUCTION

The scientific rationale for an intensive study of the role of viruses in human cancer is well founded. It is not the purpose of this report to document this hypothesis, but we must point out that it is not only the opinion of this committee but of the scientific community-at-large that a virus etiology for some human cancers is probable. This point will be elaborated on because it provides an important part of the rationale for our recommendations.

In several animal species, viruses have been shown to be directly involved in cancer causation, these include sarcomas and leukemias in chickens, mice and cats, and breast carcinoma in mice. The viruses involved include both DNA and RNA-containing types. In addition, certain viruses, when injected into newborn animals, cause a variety of tumors later in life, although their role in natural populations is less clear. Similarly, many viruses, again of both kinds, cause the kind of changes in tissue culture cells, including human, that we have come to associate with malignant change. The situation, however, is complex, for despite the fact that these results are not too surprising--since in essence viral infection or expression is the impingement of one genotype upon another genotype--we know from detailed studies of viral infections in bacteria that there are a variety of ways in which virus infected cells can be heritably changed. These include transduction (the transfer of genes from one host to another) conversion (the change in a variety of cell properties upon lysogenization) and mutation (the insertion of a prophage into a gene, thereby inactivating it).

Viruses can be transmitted in populations both vertically and horizontally. Vertical transmission can either resemble the inheritance of any other gene or alternatively be the result of congenital transmission from parent to progeny. Horizontal transmission of viruses is similar to the transmission of any other infectious agent.

At present there is no positive and considerable negative epidemiological evidence that cancer in man is an infectious disease. Also, despite much effort and expenditure of funds, no definitive human cancer virus has been isolated.

Why then go on? There are several good reasons. For one, the understanding of how known cancer viruses produce malignant change in other living forms could reveal unsuspected approaches to human cancer. Secondly, because of the complexity of some oncogenic viruses and their mode of inheritance, it is possible that in an outbred population such as the human one, it will be difficult to find viral particles per se or a host to grow them on. Again, there is no scientific rationale at the moment why what is true for other mammals should not also be true of humans. Furthermore, if viruses or viral gene products are involved in human cancer, specific diagnostic, preventative and curative procedures might then be available, although even on this point we should not be too sanguine. A final point must be made. At the present time the most rapid and reproducible way to change experimentally a normal cell to a cancer cell is by infecting it with certain viruses. Moreover, in some instances specific viral gene products have been implicated. Thus, for the first time in the long history of study on cancer etiology, a specific agent causes a known tumor with a high probability. From the point of view of understanding how a transformed cell differs from a normal cell, viral infection confers a tremendous advantage for basic studies. The tumor cell caused by a given virus always presents the same immunologically recognizable changes. It may therefore be possible to determine what chemical changes in a cell are responsible for at least one cancer phenotype. Basic studies with other carcinogens may not be as experimentally simple and useful as are studies with oncogenic viruses.

The question to be considered then is not whether viral oncology, broadly defined, deserves support but what are the best mechanisms to support research in the promising area of viral oncology.

## VIRAL ONCOLOGY AND THE SVCP

Since in many ways all studies of cell biology, virology and certain areas of immunology and genetics relate to our understanding of cancer, it is difficult to analyze NIH support for viral oncology. The figures given to us by the SVCP, imply that for F.Y. 1972, approximately $120 million was awarded in support of approximately 2,000 grants in the area of virology in all of the NIH, of which about $58,000,000 went to studies which are in some way related to cancer. The support of viral oncology within the National Cancer Institute but outside the SVCP was about $7 million for about 100 grants. The SVCP distributed $42 million through 131 contracts in F.Y. 1972. Clearly the SVCP funding of viral oncology overshadows the same area in NCI as a whole and approaches the total NIH effort. However, it supports only a small fraction of the relevant scientific community.

This brings us in essence to the charge of this review committee. Should this single funding instrument as it currently operates have so large a fraction of the resources that support cancer virology at its disposal? It is the view of this ad hoc committee that the answer to this question is "No". Since we also believe that the funds available through the SVCP are appropriate, the rest of this report will attempt to justify this conclusion and offer a series of recommendations as to how the SVCP should operate in the future in order to maximize its impact on viral oncology. These recommendations are designed to take advantage of the ideas and efforts of a much larger segment of the scientific community.

## JUSTIFICATION FOR THE SVCP

The SVCP was set up in 1964 as a special contract program within the NCI "on the conviction that there existed sufficient knowledge and information and technical capability to plan and implement an intensified coordinated program, the main objectives of which were to: 1) determine whether viruses comparable to those known to induce cancers in laboratory and domestic animals are also etiological agents of human cancer, and 2) to develop effective means for the prevention and/or control of human cancers when such etiological agents are found." It is now 10 years, and a quarter of a billion dollars later, and the same two objectives remain. It was the assumptions that were wrong. There did not, nor does there exist, sufficient knowledge to mount such a narrowly targeted program. Basic ignorance of the mechanism involved in the cancer process, even in animals where a viral etiology is definitively established, is so profound that it is difficult to be certain where to begin, much less organize a focused attack.

We do, however, agree with objective (1) as an appropriate and high priority goal for an NCI program independent of the original assumptions. Early on the SVCP was focused on this point, and the contract program was initiated to facilitate work in this direction which clearly could not be done through the grant mechanism. Large screening programs, production of high quality standardized reagents for general distribution, procurement, storage, and distribution of optimal clinical materials, and increased coordination and information flow between investigators were seen as objectives requiring a unique mechanism for support and administration. It is in precisely these areas that the SVCP has made significant contributions to viral oncology.

Objective (2), although the obvious goal of the program, is where the serious and destructive aspects of the SVCP approach have their roots. The underlying assumption was, and in large part still is, that once human cancer viruses are found, they will be controllable by anti-viral vaccines. The analogy with the control of poliomyelitis is the guiding principle; that is, that knowledge of the virology and natural history of the infection is sufficient to achieve control, and that detailed understanding of the disease mechanism is unnecessary for the successful outcome of the program.

Unquestioning acceptance of this assumption would justify the conclusion that most of the basic information needed to solve the cancer problem is already at hand, that a directed program can achieve the objective, and that a definitive result can be obtained within a relatively short period of time. It is apparent that the NCI gave relatively high credence to this assumption.

In short, we agree with the goal of identifying human cancer viruses and evaluating their role in the etiology of cancer, but reject the concept that this holds sufficient promise for a short term solution to the cancer problem to justify compromising basic research in this and other areas. The search for cancer viruses is an essential and feasible part of the long range attack on cancer, but must be viewed as a high risk, high payoff gamble in terms of short range benefits. Even a restructured SVCP should be an "in-addition-to", rather than an "instead-of" program.

Another justification for the program that was given was the necessity to interest the scientific community in the problem. This may have been true in 1964 but is not today. With progress in the cellular and molecular areas of biology, which earlier came mainly from work with bacteria and their viruses, the natural evolution of the science was to move to the more complicated cell. As probes of cell function, viruses have no peer. We now see a generation of biologists trained in the biology of prokaryotes, moving on to use their skills in the analysis of the eukaryotic cell. Fortunately the necessary technology to handle such cells and their viruses was also developed during this period, so that an unplanned but obvious "convergence" of effort is now in progress. With rare exceptions it is the nature of scientific endeavor to move, given the freedom and funds, in the direction that it can move. New discoveries are quickly integrated into the body of knowledge and exploited by the imagination and work of the best scientists.

## CURRENT STRUCTURE AND REVIEW PROCEDURES OF SVCP

The original direct scientific targets of the SVCP, such as evaluating adenoviruses as causes of human cancer, were relatively clearly defined, and relatively easily managed. Perhaps for the reason described in the preceding section--acceptance of the notion of an easily obtainable cancer vaccine--the program grew both in funds and scope. This is now exemplified by the complex research-logic-flow chart. It contains targets that are far broader, are longer range, involve model animal systems, involve searches for candidate viruses and encompass a wide range of basic research areas. All of this is managed from in-house, with the great majority of currently funded contracts solicited by the NCI.

The current organizational structure of the SVCP divides it into several segments, including Biohazard Control, Breast Cancer, Developmental Research, Solid Tumor Viruses, Tumor Virus Detection and Viral Immuno-Epidemiology. Supporting these is the Office of Program Resources and Logistics. Each segment has a Program Segment Chairman, a supporting staff, and a working group for scientific review.

In a meeting chaired by the Associate Director for Viral Oncology, the Program Segment Chairmen and their staffs meet once a month for discussion of policy and review of new and renewal contracts. This group votes on each contract, primarily on the basis of relevance and need. The vote for approval or disapproval is open; if approval is voted, there is a secret ballot for priority level. Voting members in the Segment Chairman's group include the Segment Chairman and Vice-Chairmen, plus three or four NCI staff (administrative personnel). If the contract receives a sufficiently high priority level, it is then submitted to a working group for scientific review. We asked Dr. W. Rowe to attend one of these meetings and quote his letter to this Committee:

"I attended a half-day of the meeting, during which time 6 contracts were discussed. In these discussions several positive features emerged, the common denominator of which is that the Segment Chairmen take their jobs seriously, and try to be conscientious in overseeing the program. Serious scrutiny was given to the question of whether one particular contract would not be much more appropriate to a different segment; for another contract, the suggestion was made that it might be transferred out of SVCP to the Immunology program under Bill Terry; another contract was strongly challenged because of the lack of publication in the past two years; a site visit was suggested for one contract. The scientific aspects of the contracts were briefly outlined, and a number of suggestions were made about what techniques and directions the contractors might find useful. There was essentially no discussion of budget, other than one contract being called into question because of low productivity in relation to cost.

I had several negative impressions, most of which happened to relate to the discussion of a contract with Life

Sciences, Inc., studying the interrelation of C-type viruses and the Marek herpes virus in germfree chickens and the nature of Marek's disease. First, I had the strong impression that none of the Segment Chairmen had any first-hand knowledge of Marek's disease; this feeling resulted chiefly from the lack of any attempt to put this work in context of the whole field of Marek's disease research--it felt as if this contract was the only information there was on this disease. I am sure that many situations are bound to arise where an important field develops which is not in the areas of expertise of the Segment Chairmen, but there is no mechanism to try to deal with this problem. Second, one of the Segment Chairmen objected to this contract as not being sufficiently relevant to the goals of the SVCP, on the grounds that the immunological system of the chicken is so different from that of man that it is not a valid model. Since the SVCP does include model systems in its domain, this is a disturbingly narrow interpretation of models. Fortunately, the other Segment Chairmen did not share this view. Third, in the course of discussion of the impact of possibly phasing out this contract, mention was made that this company is entirely supported by its three SVCP contracts. This seems to create a dangerous situation where cancelling a contract could destroy a company; any personal loyalties that may have developed could become overriding.

Another negative aspect is that in several cases the scientific justification for renewing some of the contracts was recent preliminary findings. No hard data were presented, and there was no critical evaluation. Perhaps this is considered the role of the working groups, but from my experience on such a group, this would not take place. This problem is probably due to the concept that the role of the contract program is to speed up the pace of research. I am sure that this lack of step-by-step critical evaluation leads to inefficiency in granting of funds."

We have here pinpointed one of the most serious weaknesses of the program. The Segment Chairmen have too much power. The whole program is in large part primarily an NCI in-house operation, and those who run it are also often the recipients of large amounts of the money they dispense (see below). They tend to come from a narrow section of the scientific community and certainly were not originally selected for NCI employment on the basis of their ability to run large contract programs. When the Segment Chairmen decide that a particular scientific problem should be studied, usually this study is delegated to a friendly colleague. This is not necessarily bad, but can lead ultimately to problems. For example, when the work is finished or the contractor fails to produce, understandably it becomes difficult to terminate the contract. Again, since the contracts generally involve large amounts of money, an equity is developed in the work of a particular contractor. Failure on his part leads to an attempt to prop up his program with more money support instead of more appropriate phasing out or termination. The information we received indicates that it is more difficult to terminate a bad contract than an unproductive grant.

Contracts which have been approved by the Segment Chairmen are then presented to one of the segment working groups for review. Except for the Biohazard and Breast Cancer segments (smallest units) there is no programmatic theme within the segments. The same kinds of work are done by contractors in each of the other segments. The rationale for the distribution of a particular contract to a particular working group has never been made clear to us; it appears to be determined by the interests of and perhaps personal relationship to a Segment Chairman.

The working groups have been chosen by the Segment Chairmen for the most part from the small pool of contractors and NCI people. Thus their backgrounds and areas of competence tend to coincide with that of the Segment Chairmen. Interviews by this ad hoc committee with members of these working groups disclosed that they found this work unrewarding and unsatisfactory. They had little knowledge of the program in total, felt powerless to suggest changes, and felt a great deal of unease at the lack of critical review. When asked to compare their experiences on program segments and on grant study sections, they replied that in their work on the latter the peer review was serious and stringent, whereas in the former it was perfunctory. They were hard pressed to recall if they had ever rejected a contract. In addition, one member of a working segment who also served in study sections, wrote to the committee that he considered the working segments he serves on a "farce" when compared to study sections. He maintained that less than half of the contract proposals would have been funded by a real peer review.

Drs. Defendi and Zinder attended one meeting of the Solid Tumor Virus working segment and their observation of its mode of operation confirmed the testimony we had received. Only six contracts were to be reviewed that day. Most of the time was used by oral presentations by either the Principal Investigator or the Project Officer. The questioning was quite gentle. One had the impression that since there was to be an oral presentation the proposals had not been read by the committee. The contractor or project officer was then asked to leave and a perfunctory discussion took place. No hard questions were asked about the scientific contents of the proposal, the past productivity of the contractor or the program relevance. The budget was not even mentioned, let alone analyzed. It should be noted that nowhere in the proposals or in the contract summary sheet was the total support of the laboratory given. Even when some reservations were expressed about the competence of the contractor and his group in various of the proposed areas of research, the remedy suggested was that new people might be hired to cover these areas rather than seek a more appropriate contractor. This is a strange interpretation of what a contract should be. One contract was renewed with only a nine line summary of the proposed work. The suggestion was made that the contractor be informed that next time he had better write a more detailed proposal. All contracts were approved with no priority considered. Clearly funds were available and the committee considered that these matters had been settled beforehand.

In recent times the peer review study section system has come under attack for being solely a judge of scientific merit and having little impact on programs. The members of this review committee who have also served on study sections believe that more program relevance and direction comes from study sections than from these segment work committees. Suggestions from the study sections for experiments and even modification of direction are often transmitted to the Principal Investigator. During our attendance at the Solid Tumor Virus working segment meeting, Dr. Hayflick, a Principal Investigator with a contract up for renewal, asked the committee for some guidance. He provides the Mycoplasma testing service and felt that he could not handle more than a certain number of tests per year. He was advised by the committee to restict his service to SVCP contractors. Considering that this is an important service to those working with cells and viruses in culture, one might have thought that consideration would have been given to how his operation could be expanded or another contract let. This lack of consideration of the problem was most surprising, for it is precisely in such areas that contract programs have proved to be most effective and useful, a matter to which we will return later.

Admittedly some of the foregoing discussion is anecdotal, we attended only one meeting of the Segment Chairmen, and one meeting of one of several working segments. However we did interview 10 members of working segments, received a phone call from another and a letter from still another. This collective experience bears out our general conclusions.

It seems rather paradoxical that peer group evaluation is given by people who openly express dissatisfaction with the procedures and confess to have no input into the program. This may be a natural outcome of the fact that members of the working groups are generally also recipients of generously funded contracts. There is also a trend for new members of the working groups to become contractors. Until last June contractors often sat on the same committee which reviewed their own contracts. The new directive from the NCI eliminating this situation has therefore caused some reshuffling of the committees. However, they are still drawn from the same small pool, and since a Segment Chairman has a degree of control over contracts in other segments, contractors who sit as members of working groups may well feel inhibited from being fully critical. Being only human, the contractors on working groups are in an almost untenable position.

It was only natural that when the SVCP was formed a small group of investigators was involved--an "in group". It now represents a somewhat larger "in group" of investigators. Administratively its procedures lack vigor, are apparently attuned to the benefit of staff personnel and are full of conflicts of interest. Because the direct targets have become fuzzy since 1964, although the available funds for the program continued to grow, the program seems to have become an end in itself, its existence justifying its further existence. In doing so, it is eroding what is good in both the grant and contract mechanisms, a fact which may account for the wide spread antipathy to SVCP in the scientific community.

## CONTRACT ANALYSIS

There are essentially four types of efforts that are funded by the SVCP. These include: 1) resources and services; 2) extramural extensions of in-house work; 3) large departmental or program project grants; 4) something akin to the average research grant.

### Resources

The contracts for resources are generally given to private industry or hospitals. They contract to provide standard virus preparations, antisera to whole viruses and to certain specific viral components, standard cell cultures, and animals of known genetic constitution. Hospitals provide fresh biopsy materials. In addition, there are certain testing programs such as screening for mycoplasma, screening sera for the presence of particular antibodies and testing cell cultures, virus stocks and animals for viral contamination. These resources and services are provided upon request to, in decreasing priority, in-house scientists, SVCP contractors and other scientists. Appropriately associated with these contracts are research efforts to improve production, etc.

This ad hoc committee initiated a survey to ascertain the usefulness of this part of the program. From a mailing list of 300 persons, about 200 responses have been received to date. Several significant points emerged (see Appendix 1). The recent consolidation of this area of the SVCP into the Office of Program Resources and Logistics, rather than being spread through the various segments, has resulted in a marked improvement in the service. With few exceptions, all of the respondents maintained that these resources were indispensible for their programs. They either did not have the expertise or the facilities to prepare these reagents or maintain the animals themselves, or it would have required an inordinate amount of effort on their part to do so. For the most part, the requests were handled expeditiously. The consensus was that except for certain viruses the quality of the materials was good to excellent. This latter statement must be qualified only in the sense that many did not comment on the quality. From the absence of complaint, we can assume that they were satisfied. The survey as written by the committee contained essentially five questions: what did you request?; what did you receive?; what was the quality of the material, do you know who prepared the material and what was the usefulness of the resources relative to preparing your own materials. Unfortunately, when the Office of Management and Budget rewrote the questionnaire, the first three questions were fused into one, probably causing some confusion. The raw data will be given to Dr. J. Gruber of the Office of Program Resources and Logistics, to provide him with the kinds of information that the recipients desire when receiving reagents, etc. and the names of contractors whose quality control might be questionable. It is surprising that such feedback is not already built into the program.

Although we must carefully separate in our thinking the provision of resources and services from the scientific use to which they are ultimately put--the latter depends on the competence of the investigator--we have here evidence for what a contract program can best do for the scientific community. Many contractors unselfishly commented that they would like to see these resources made more widely available.

Intramural Extensions

This is perhaps the most difficult area of the SVCP to analyze, for it touches in part on the role of Project Officer. Since this is a contract program, each contractor is assigned a Project Officer from the NCI scientific staff. The role of Project Officer varies from unawareness of his position as such, through benign neglect, to overseeing the day to day operations of the contract. Nowhere in the contract proposals, reports or analyses per se is it possible to determine his role precisely. However, from the information Dr. Guss has provided, and our own analysis, the extensions of intramural activities of project officers are those of, 1) Dr. R. Huebner at Microbiological Associates, Flow Labs and to a lesser extent at the University of Southern California; 2) Dr. G. Todaro at Meloy Labs; 3) Dr. C. Boone at Meloy Labs; 4) Dr. R. Gallo at Litton-Bionetics; 5) Dr. S. Aaronson at Hazelton Labs; and 6) Dr. R. Bassin at Litton-Bionetics. The aggregate funding of these operations is over $10 million per annum or about one-fourth of the toal program. We may note that for the most part these contracts are with private industries located in the Bethesda area. In addition, some other NCI staff scientists work at these various laboratories. The arguments given in conversation with the NCI people in favor of such an arrangement are that (paraphrased quotes from various individuals) "it is impossible to work at the NCI itself as there is no space, the buildings there are poorly designed, federal procurement procedures are terribly slow, the NCI is filled with old fuddy-duddies--etc. etc." It should be pointed out that some of these scientists are very creative individuals who make important contributions to science.

However, even if all the science were of the highest quality, which is not the case, there is much redundancy and overlap in the work scope and the contracts themselves are very diffuse about the goals. They are extremely difficult to analyze because they contain so many disparate elements. Many are almost miniature reflections of the total SVCP program.

We seem also to have the peculiar situation of NCI staff scientists writing contracts for private industry, the monies from which are used to support their own work. These contracts go for first review to the Segment Chairmen Committee of which they are often members, and then to the working groups, which they may either chair or sit on and which often contain close friends and colleagues. NCI staff scientists also move about from one of these local contractors to another, in what can only be interpreted as an effort to support these contractors. Further comment on such modes of operation would be superfluous.

We can only guess that having to "review" contracts of the type described above accounts in part for the sense of frustration felt by some members of the working groups. No one really likes to spend his time acting as a rubber stamp.

## Program Project Grants

These represent large contracts which essentially buy the output of an entire university department. They pay the salaries of all personnel from the professors to the janitor and provide the equipment and materials for all. When judiciously chosen they can free a principal investigator from financial worries for a number of years and allow him to try out new and innovative procedures without fear of loss of funding due to failure. Competently performed experiments even with negative results are often of great import. Some of the best science in the SVCP, and some of the most pedestrian, is currently carried out under such contracts.

The difficulty in evaluating such contracts results from the fact that they generally contain a large number of incompletely described subjects for study. These can include electron-microscopic surveys of biopsy material, reverse-transcriptase assays, the isolation of virus mutants, and on and on.

In this aspect they resemble the large diffuse contracts of the intramural extensions. It is clear that the principal investigators feel that in order to justify the large amounts of monies needed to fund their large staffs, they list in their proposals everything that is currently in fashion. Such unrealistic and diffuse proposals would be rejected by study sections on these grounds alone. It is strange that they are supported by a contract program which is supposed to have a clearly defined goal.

### Small Grants

Of the contracts, a small fraction monetarily, but perhaps some of the most productive scientifically, are analogous to simple research grants. In principle, such contracts could be used as add-ons in fundings to the best investigators in order to allow them to try out scientifically novel but risky approaches. The difficulty lies in the fact that many of these contracts are not of this kind but rather support Principal Investigators whose proposals received modest review in study sections, according to members of study sections who have had the opportunity to see them at both the grant and contract level. Such contracts also often have the flavor of continuation of the principal investigators'ongoing endeavors, sometimes with slight changes for program relevance. It must be recalled that under the rubric of cancer research almost any research in cell biology or virology could be fitted.

## SUMMARY

The question has been asked of this committee whether the research sponsored by the SVCP is of the same quality as that under the grant system. Our answer is implicit in the analysis given above. More explicitly, in the reviews by members of this committee of the larger research contracts the words "overblown", "overambitious", "too diffuse", "high cost relative to yield" recur over and over. There seems to be some redundancy in the contracts for resources. These contracts as currently written, generally do not indicate the nature of the quality control that is employed or the rationale for particular production methodologies.

We are quite sure that much more would have been accomplished if equal support had been provided on a competitive basis to many more laboratories with greater capability and experience in particular areas. We illustrate this point with the following example:

In analyzing the large contract to Flow Labs and following a site visit, the Chairman of this ad hoc committee found that one of the major endeavors at the moment is in the amino-acid sequencing of the gs antigens from a variety of RNA tumor viruses. This contractor had hitherto no expertise in protein chemistry, and therefore two years ago it became necessary for him to buy all of the heavy equipment needed and to hire new personnel for this task; it is very expensive to set up such a laboratory. Since this is an important scientific problem, the Chairman of this Committee asked a number of very competent protein chemists what might have happened had a widely publicized Request For Proposal gone out in this area. Were all the good protein chemists so busy and their machines so completely in use, that analysis of other proteins would not have been considered? He was told that no protein chemist can afford to keep his machines running full-time, nor could he sustain the personnel and reagents to do so. Thus, given modest amounts of money for a few technicians, reagents and materials, established protein chemists might have considered undertaking this project. The SVCP not only had to set up a new laboratory but perhaps, more importantly, may have lost the opportunity to interest another segment of the scientific community in the cancer problem.

## RECOMMENDATIONS

Since our review of the SVCP has a negative tone, one might suggest that the program be abandoned. We feel that this would definitely be a mistake. The original notion that there ought to be an integrated program on the study of the relationship of viruses to human cancer was, and still is, a good one. The mistake that led to the excesses we describe was primarily one of management. The program was allowed to grow from the inside out. The vision that established the program was sound, but the underlying philosophy that the role of management of fundamental science is the same as the role of management for engineering or development when the fundamental knowledge is available, was sadly in error. Instead of allowing the direction of the scientific program to come from the working scientists by opening it to all, the program appears to have been a closed operation from its start.

Success in science is an irregular and unpredictable phenomenon. When and where important discoveries are and will be made is almost impossible to determine in advance. The goal should be to maximize the opportunities. This of course does not assure success; all that can be stated is that if experiments are not done there certainly will be no success. Were success assured it would no longer be a question of science. Therefore, our recommendations have as their goal the opening of the program to scientists at the program, decision and working levels.

We believe that there are three features of the SVCP that should be conserved:

1. It should remain an integrated program where communication and collaboration are encouraged between the investigators by frequent meetings at which projects are discussed. Program Chairmen can serve as fairly selfless catalysts in a way that executive secretaries of study sections cannot. The receipt by contractors of the summaries of the annual reports of all other contractors cannot help but be stimulating, although here we strongly recommend that an analytical index of the summaries be prepared. This will serve not only contractors, but also segment chairmen and review committees, as a means to achieve natural collaborations and the avoidance of a redundancy of efforts.

2. The program should continue to provide standardized reagents, viruses, cells and animals in addition to providing certain supportive testing programs for the investigators. It is clear that few laboratories could provide these for themselves without developing peripheral facilities which would only consume time and money and inhibit many lines of research.

3. There are kinds of developmental research and clinical and animal screening programs that could never compete in the current study sections for funding, but which are absolutely necessary and therefore can only be supported by an integrated program.

To achieve the above stated goals we make the following recommendations to serve as a guideline for restructuring the SVCP.

The Intramural Program

1. A Steering Committee shall be appointed by the National Cancer Board to provide overall administrative leadership and guidance. This committee shall consist of the Segment Chairmen and a number of scientists greater than the number of Segment Chairmen. These scientists should be appointed from outside the NCI and would serve no more than four years. They should not be recipients of support from this program. They should approve the appointments of new Segment Chairmen and members of the working groups. They should assist in setting priorities for the research efforts of the program. They should oversee the segments and have the responsibility for reorganization of segments as new developments in the field may warrant (see below, 8).

2. The Office of Program Resources and Logistics should be maintained much as it is. The recent removal of these resources from the control of the segments themselves has met with universal approval. Time did not permit detailed analysis of possible redundancy in the contracts relating to services and reagent preparation, but it seems to exist. Quality control could be improved. Simple feedback to this office after receipt of materials by the investigators would provide a quick indicator of any developing problems. The Chairman

of this segment should have an advisory board including NCI personnel, individuals from other relevant areas of NIH and some outside scientists. These individuals should have some expertise in the problems associated with reagent production and testing. They should set up standards for monitoring quality control.

The availability of materials and services should be widely advertized and open to the scientific community-at-large, and provided on the basis of merit. No longer should highly qualified scientists be unable to obtain certain reagents simply because they are not in the program.

This office should be sensitive to recommendations that may arise from the working groups for the types of resources that are needed. It should report regularly to the Steering Committee to discuss the determination of priorities, both for reagent production and distribution.

3. With regard to the intramural program, we did not feel it to be in our purview to look into the allegations of some of the NCI personnel regarding the difficulties in working on the "reservation." This is perhaps an area that the Cancer Board might want to look at more closely. However, we feel that all NCI staff should work either in space on the reservation or if necessary in space and with services rented on the outside. Their funds should come from the NCI in-house budget, not from the extramural program. They should be subject to the same rules as other NIH scientists. NCI

staff should not be put in the embarrassing, if not illegal, position of writing contracts for other contractors to support their own work. We do strongly support the continuation and strengthening of the in-house viral oncology program. It should be provided with adequate space, personnel slots and funding. Competent personnel would then be readily available to provide advice to the Office of Program Resources and to outside contractors.

## The Extramural Program

4. During the course of the next two to three years, all working groups should be reconstituted. Since except for the Office of Program Resources and Logistics we do not at this time see a logical division of the segments, we would favor setting up about five working groups. Each is to have a Segment Chairman salaried by the NCI and, if possible, chosen from the outside scientific community, with counsel and approval from the Director of NCI and the National Cancer Board. Should the current Segment Chairmen choose to continue to serve they should give up their roles as in-house program managers.

5. The working groups should consist of more than half non-NCI personnel appointed for a maximum period of four years, and initially mainly of scientists not currently in the SVCP. One can envision such groups as consisting of 2 cell biologists, 2 animal virologists, an immunologist, an

oncologist-physician and a geneticist. They should be chosen by the Steering Committee.

6. These groups should have the authority to rate priorities, including refusal or decreased funding of proposals. They should see all of the submitted proposals and letters of interest and be advised of their fates. There should be no overriding of their decisions without justification.

7. These working groups should be composed of people who are willing to give up many other activities while serving. The meetings of the working groups should not only consider the current set of proposals but have sufficient time to participate in program direction. They should have the authority to generate proposals. Thus they should meet at least once a year with the Steering Committee.

8. Under the guidance of the Steering Committee, these working groups might evolve in time, as developments in the field warrant, into segments with a particular programmatic theme.

9. All current contractors should be notified that their contracts will be terminated over the next three years.

10. A public and widely advertized announcement should be made to the scientific community that the Viral Oncology Program is open to proposals. Current contractors can of course compete. This procedure will not only allow the weak contractors an opportunity to seek other funding or make other

arrangements, but also have the salutory effect of making even potentially successful contractors rethink their programs. What has amounted to almost automatic contract renewal can only have had a stultifying effect on the current contractors, accounting in part for the poor quality of some of the research done to date. A little competition should be stimulating.

11. These proposals would then come to the newly constituted working groups and be distributed more or less at random for consideration. The Segment Chairmen might distribute some on the basis of special expertise available in a particular working group.

12. The procedure of inviting the Principal Investigator or his Project Officer to present his work should be abolished. It would leave more time for deliberation. Also it is difficult for even the most objective of us to turn down an individual who was earlier in the room presenting his case. When necessary, site visits can be arranged.

As we discussed in the Introduction, considering the scientific promise of viral oncology, it is appropriate that the NCI continue to allocate some 10 percent of its budget to this program. However, we have intentionally avoided describing the mechanism of funding as either contract or grant. We have found only contradiction and confusion between these two mechanisms as currently understood and interpreted by contract officers on the one hand, and contractors on the other. We stress rather the integrated and coordinate nature of the program; some proposals must be contracts--those to private industry--while others can be called whatever seems appropriate. The common theme is the effort to determine the role of viruses in human cancer; format should not be allowed to stand in the way.

## GENERAL COMMENTS

Although this committee could not interpret its charge to include the general scene in the suport of biomedical science today, we feel we would be remiss if we did not bring to the attention of the National Cancer Board certain features that disturb us. Simultaneously with the growth of targeted or non-investigator initiated programs, the support base for fundamental science is being eroded. Perhaps in no area ~~as~~ [illegible] in Cancer Research is ~~is it necessary for~~ a strong and broadly based biological research endeavor necessary. It is more than possible that none of our current approaches to the problem are on the right tack simply because we lack the fundamental knowledge to see even indirectly our way to the clear water. Not only is generalized grant support in areas critical to Cancer Biology being decreased but also training programs from which our future scientists are to be derived are also being undermined. Where are the researchers of tomorrow to come from? Large targeted programs usually are not the proper environment for training of new and creative scientists. They tend to lead to niche filling, thereby inhibiting the development of investigators who can think independently.

We support the National Cancer Board in its efforts to restore training grants and would recommend that it similarly use its influence to promote the general health of biomedical research throughout the NIH.

While recognizing that budgets must be prepared years .

in advance, the Board should do its best to see that at least within the NCI, funds can be transferred from one area to another when the quality rating of proposals merits reallocation.

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

TO : The Record

DATE: March 26, 1974

FROM : Executive Secretary, National Cancer Advisory Board, National Cancer Institute

SUBJECT: Zinder Report

It should be noted that the draft version of the Zinder Committee Report, submitted for consideration to the National Cancer Advisory Board on November 27, 1973 and subsequently referred back to the Zinder Committee for finalization, was resubmitted to the National Cancer Advisory Board on March 19, 1974, in identical form, as the final report of the Committee.

R. A. Tjalma

Richard A. Tjalma, D.V.M.

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# MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

TO : The Record

DATE: March 26, 1974

FROM : Executive Secretary, National Cancer Advisory Board, National Cancer Institute

SUBJECT: Action to create and charge an ad hoc Board subcommittee to review, and advise the Director, NCI, regarding selective implementation of recommendations specified in the Zinder Committee review of the Special Virus Cancer Program of the National Cancer Institute

During the course of the March 18-20, 1974 meeting of the National Cancer Advisory Board, it was proposed and approved that a Board subcommittee be created to review the Zinder Committee report of the NCI Special Virus Cancer Program. Such review is to be directed to evaluation of specific recommendations as set forth in the report and selective endorsement of same for referral, through the Board, to the Director, National Cancer Institute, for implementation.

Implementation of approved recommendations is to be accomplished through cooperation and consultation with the Director and staff, National Cancer Institute; the subcommittee will report to the full Board, at future meetings, the progress of measures initiated by the Director, National Cancer Institute, in response to report recommendations endorsed by the National Cancer Advisory Board for implementation.

R. A. Tjalma

Richard A. Tjalma, D.V.M.

Comments by Dr. Norton Zinder, Chairman, Committee to review the Special Virus Cancer Program of the National Cancer Institute, to the National Cancer Advisory Board, meeting of March 18-20, 1974.

Before touching on the substance of our report I've a few comments to make. When we were asked to review the V.C.P. last year I expressed the following sentiment to the Committee. I told them that I was somewhat skeptical of the National Cancer Plan for the kinds of reasons that were discussed in the Thomas Committee report. These included the enormous dangers in over-promising the Congress and the public, the seeming over-emphasis on central planning, the potential danger to the biomedical research establishment it might cause by dislocating biomedical research in general, and also the lack of the operative section of the Plan. I should say that I was privy to this report as a member of the Report Review Committee of the National Academy of Sciences. Therefore, our own report had to be parochial in that we were looking at only a segment of the program almost of the context with its totality and were reviewing one segment without knowledge of the workings and planned workings of the others, a task which of course would have been enormous and beyond our powers. I introduce my remarks in this way to indicate that we took our review seriously, for we felt that given a National Cancer Plan we might in some small way attempt to see that it was the best plan possible.

While the document which we submitted lists our more formal operations such as meetings and site visits, it does not indicate the consultation that committee members had via the telephone and in letters. As our review proceeded various members would be in touch with me as their thoughts developed.

It is from these letters and discussions in addition to our meetings that the report was synthesized. The committee stands together on the document that you have received and considers it our report.

Now to touch on the substance. We can divide it into two areas, the analysis and the recommendations. The committee unanimously felt that viral oncology was a subject worthy of high priority effort. Viruses of a number of kinds have been implicated in cancer of many animal forms and some small amounts of evidence implicates certain viruses in human cancer. Also, viruses provide a potentially clean model system for studying in depth some of the details of the oncogenic process but of course not independently of the total gestalt of cancer.

In our review of the V.C.P. and I must emphasize it was a review and not an investigation, it became clear early on, and probably is also a truism on a priori grounds,that high productivity from a research program so broad in scope, is essentially impossible when control is largely in the hands of a few individuals. There is an inordinate amount of power in the Segment Chairmen's group. It is this power that is responsible, for real or imaginary reasons, for the tensions that exist among contractors in the program and accounts for the antipathy to the program in the scientific community. We assume that the intimations of this tension was what motivated this Board to initiate the review. We can assure this Board that this tension and antipathy does exist. In our survey of the Resources Program a number of comments on the management of the Program, mostly unfavorable, came in. I've forwarded to Dr. Rhoads copies of these comments.

When we interviewed the contractors who were also on the contract evaluation working groups, their comments were markedly circumspect compared to what they said privately. You have all received a transcript of this meeting. We think it speaks for itself. Let us realize that these individuals were talking to the whole committee with the comments being taped and stenotyped and a member of the V.C.P. present. Still, they provided us with a clear indication of how powerless they felt and how unsatisfied they were with the review. You can judge for yourselves. In answer to Mr. Schmidt's question posed to this committee about the quality of review, we feel that it has been extremely poor. However, because of the existence of our committee some members of the working groups have told me that they now feel in a stronger position to make suggestions and oppose decisions.

When we say that the Segment Chairmen are extremely powerful one must recall that Drs. Manaker, Huebner and Todaro, the Segment Chairmen of the three largest research segments are also in-house program managers and project officers for seven or more contracts in addition to their roles as Segment Chairmen.

With regard to the Science supported. When members of the working groups imply that they are not satisfied with the kind of work supported, this should almost suffice. Our own analysis is that about 50% of the program is supportable at some level. Those of you who were here last time may recall that Dr. Price rated all of the contracts and either in dollars or number of contracts gave about 50% a priority of 3 or better even when correcting as we all did for the fact that some of the work, screening, production, etc. must be pedestrian in nature.

There has been some comment that we did not document our statements. Indeed the report was written in general terms as we well realized that one could not provide evidence in any real sense. I again emphasize we were a review committee and not an investigating committee. We were asked to take an overview and these are our carefully considered best opinions. With regard to the letters we received, contract analyses etc.--they were not submitted as part of the report since we presumed the report to be a public document and we felt that the same kinds of discretion that one uses in handling reviews of contracts or grants or recommendations etc. should be maintained. We did forward to Dr. Rhoads in addition to the comments I mentioned before, all of the external correspondence that was received including the transcripts of the meeting with the Segment Chairmen and some of our own contract reviews. Since it has been our experience that all documents with wide circulation somehow diffuse even further, we felt that these should not be part of the body of the report as especially with the contract analyses, and comments on individuals--specific contractors--were made. These documents were also for our own internal discussions and edification and not finished reviews.

In considering our recommendations to this Board, there was some sentiment in the committee to recommend that the V.C.P. be restricted solely to Resources and Procurement and those developmental efforts for which it was possible to provide a realistic specification of the effort involved to a singular desired objective. In addition those aspects of the program which are research in the sense that they add to our fundamental science base should be removed and the monies saved thereby reallocated to the grants program. However, on reflection we did see advantages to a collaborative and integrated program on viral oncology as long as the program was open and competitive.

There seems to be some confusion in terms on the issue of grants versus contracts. We see no reason why such an integrated collaborative program must be supported solely by the ~~contracts~~ contract mechanism--and I now use the words contract mechanism in the only sense that I can understand their operational meaning--decisions being made by a few in-house people as to what and who is to be supported.

Thus we recommend to the Board an integrated program with a built in series of checks and balances to prevent the special notions of particular individuals from carrying the day. For example, should the first definitive cancer virus turn out to be a papova virus, the V.C.P would be in a strange position. It scarcely supports any work in this area and only recently has gotten seriously involved with the DNA viruses such as Herpes. In this light I will make just one remark with regard to the V.C.P. fact sheet. The V.C.P. takes credit for the distribution of EBV virus. Our Resources and Facilitie survey uniformly showed that the one virus that all investigato found to be useless was E.B.V. A V.C.P. is not needed to send out seed cultures.

In any event, we would suggest the following development for the future: First, the setting up of a steering or advisory committee with members not in the program that meets regularly with the Segment Chairmen to discuss program and help reorganize the working groups. Segment Chairmen should be that and no more. When the working groups are reorganized, all current contracts should undergo thorough review, not as renewals, but as if they were an initiation. Importantly current contractors should be notified well in advance that such a review is to occur. Essentially these contracts are to be terminated. We don't quite understand the so-called legal objection to contract termination. It is our understanding that contracts by definition run to term and until recently were for only one year periods. Clearly certain contractors have built up special expertise in these last years and should have no trouble competing. However, competition would be useful as we feel that with real review the monies available to this program could readily support several times the number of proposals that it currently does. Thus new proposals would succeed and some of the current ones would naturally fall by the wayside in part or in toto. Most importantly, new ideas should diffuse into the program as the complexity of viral oncology clearly necessitates.

Another important point is that intra-mural work should not compete with extra-mural research in the same program. Local industrial contractors should not be used as a way to do intra-mural work. If these contractors don't have the expertise to justify their support without staffing by N.C.I. scientists, then they shouldn't be contractors. We do, however, support the existence of strong intra-mural program in viral oncology but within the N.C.I. and subject to the same rules as other N.I.H. investigators.

Thus we envision a program in which there is an appropriate mix of contract and grant type work, all open to serious competition and decided upon by the collective wisdom of the working groups in coordination with the steering committee and Segment Chairmen.

Still one further point. The provision of materials and testing services ets. should be decided on the basis of scientific merit and not just program membership.

To close, let me just say, you have received our report, you have also received the V.C.P. reply. We are glad to see that they seem to be moving in part in the directions we recommend but they still seem to be refractory to opening the program. We are, of course, ready to answer your questions and other members of the committee might want to comment further.

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFA
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

TO : Dr. Richard A. Tjalma, Assistant Director
for Board and Panel Affairs, NCI

DATE: January 17, 1974

FROM : Associate Director for Viral Oncology, DCCP, NCI

SUBJECT: Report of the ad hoc Review Committee of the Virus Cancer Program

As requested, we are submitting comments developed by staff of the Virus Cancer Program on the draft report of the ad hoc Review Committee of the Virus Cancer Program. Additional material is included as background information for NCAB members attending the January 28 informal meeting:

Viral Oncology Annual Program Report, 1973
Viral Oncology Program Background Information Report
Transcript of the meeting of the ad hoc Review Committee of
the VCP, held June 8, 1973 in New York.

We trust this information will be helpful for our future discussions.

Dr. J. B. Moloney

Enclosures

LRS:lq

# COMMENTS ON THE REPORT OF THE AD HOC REVIEW COMMITTEE OF THE VIRUS CANCER PROGRAM DEVELOPED BY SENIOR PROGRAM STAFF

Meetings of the Review Committee:

1. March 23, 1973 - New York

   Organizational meeting. Nine of ten members present - Dr. Stetson absent.

2. May 2, 1973 - Bethesda

   All members present. First and only meeting with Chairman and Segment Chairmen of the Virus Cancer Program.

3. May 3, 1973 - Bethesda

   Dr. Rowe attended a meeting of the Program Segment Chairmen.

4. June 8, 1973* - New York

   Third meeting. Nine of ten members were present - Dr. Stetson absent. The minutes of this meeting are appended and summarized in APPENDIX A.

5. July 23, 1973 - Bethesda

   Dr. Zinder and Dr. Defendi attended a meeting of the Solid Tumor Virus Working Group, one of six working groups of the Virus Cancer Program.

   Contracts reviewed:

| | | |
|---|---|---|
| Microbiological Associates | $1,920,000 | |
| Stanford University | 131,962 | |
| Salk Institute | 70,750 | |
| Harvard University | 63,000 | |
| Wistar Institute | 131,653 | |
| Weizmann Institute | 70,000 | (to be phased out) |

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*Following this meeting Dr. Tjalma resigned because he had accepted a position at the National Cancer Institute.

6. July 24, 1973 - Bethesda

   Dr. Zinder and Dr. Defendi visited Flow Laboratories - Solid Tumor Virus Segment.

   Dr. Zinder, Dr. Defendi, Dr. Rowe visited Litton-Bionetics, Inc. Tumor Virus Detection Segment.

7. August 29, 1973 - Los Angeles

   Dr. Zinder, Dr. Porter, Dr. Price and Dr. Shatkin attended Pacific Coast Tumor Virus Group meeting.

   August 30, 1973 - Los Angeles

   Dr. Zinder, Dr. Porter, and Dr. Shatkin visited University of Southern California.

8. October 3, 1973 - New York

   Fourth meeting to analyze survey. All members present.

## RESPONSE TO THE TEXT
## OF THE VIRUS CANCER PROGRAM REVIEW COMMITTEE REPORT

In its analysis of the operations of the Virus Cancer Program, the Committee concluded that research in Viral Oncology deserved continuing support. The basic issue was whether the contract is the best mechanism for providing such support. The FY 1973 expenditure by the National Cancer Institute of 42 million dollars funding 131 contracts was contrasted with 7 million dollars in National Cancer Institute support of about 100 grants. Actually, of the 119.5 million dollars in FY 1972 NIH extramural grants, 58 million dollars supported 1090 grants covering different areas of cancer-related research. The 131 contracts within the Virus Cancer Program support approximately 600 professionals and 230 pre- and post-doctoral trainees which, when combined with technical support, total 2,290 individuals whose combined activities resulted in 1,183 publications in FY 1972. Therefore, we question whether the overall opportunities for the development of fundamental research observations in science are as limited by the additional support provided to the scientific community by the Virus Cancer Program as the Committee implies.

The Committee recognized the contributions of the Virus Cancer Program in screening, production of research reagents, and coordination and information flow between investigators which are not features of the grant mechanism. What is not recognized is the tremendous amount of basic research supported by the Virus Cancer Program that make these high-quality reagents available to investigators. However, the Committee believes that a serious and destructive aspect of the Virus Cancer Program is its assumption that knowledge of the virology and natural history of tumor virus was sufficient to achieve control of virus-induced cancer and that most basic information was on hand to achieve a definitive result in a relatively short period. The fact is that the Virus Cancer Program has never considered the virus-cancer problem to be one which would be readily resolved, and the breadth of its overall activities across different research specialties shows cognizance of the need for such contributions converging on the major objectives.

The Virus Cancer Program is and must continue to be an "in addition to rather than an "instead of" program. The basic philosophy underlying the Program was to make possible the expeditious development of significant observations generated within the scientific community to the benefit of the public and not to compromise the basic research contributing to an understanding of neoplastic transformation resulting from the imagination and work of the best scientists under the extramural grants program or other sources of support.

The Virus Cancer Program is obliged to use the contract mechanism to fund its collaborative program. This has required yearly review for renewal of projects which are regularly monitored through progress reports submitted tri-annually, and more recently semi-annually, by the contractor for perusal by in-house and Working Group members. Reviewers are, therefore, well aware of essential details of the progress made under the project in contrast to the position of Study Section members who are primarily concerned with the evaluation of new efforts. This does alter the nature of the review. Program has emphasized the acquisition of and association of the best scientists available for research who will contribute to program objectives rather than development of research for its own sake. Each contract receives review by two to three review groups followed by approval by the Institute Director, his designates, and higher authority as required. Under this system, the power of individual Segment Chairmen is minimal.

The Virus Cancer Program is primarily an in-house operation in the sense that it is the administrative focus for a collaborative program of research. Any contract support for in-house investigations receives the same reviews accorded any contract project and the in-house investigator maintains liaison through the contractor's principal investigator.

The Committee contends that the Segment Chairmen come from a narrow section of the scientific community and that Working Group members are chosen to reflect a similarly narrow range of expertise. Moreover, it was stated that Segment Chairmen were not originally selected on their ability to run large contract programs. The Segment Chairmen (appointed by the Director, National Cancer Institute) are chosen both for their ability to manage complex research programs and for their scientific knowledge in viral oncology. The Working Groups are composed of individuals drawn from a wide variety of scientific disciplines to obtain as much input as possible from a membership also cognizant of virological aspects of oncogenesis. The range of expertise so provided is not narrow, but it is attuned to virological matters since the activities of the Virus Cancer Program are restricted to problems of virus relationships to cancer.

We recognize that for some Segments names no longer reflect their programmatic theme. The Chairman of the Virus Cancer Program is considering rectification of this situation. Any specific suggestions for restructuring would be welcome.

Contract projects are not assigned to a Segment on the basis of a particular personal relationship between a Principal Investigator and a Segment Chairman. Investigators in the field might tend to favor a particular Segment because the research activities which it administrates are similar to their own. However, it must be emphasized that 14 reviewers vote independently to establish the relevance, priority and need for new proposals and renewals of on-going projects, each of which is rated by secret ballot. This policy obviates personal bias of any individual member directed for or against a project or its Principal Investigator. Furthermore, the proceedings of subsequent Working Group technical reviews are recorded for each project and are subjected to detailed scrutiny by officials authorized to initiate contract proceedings.

The Committee Report states that reviews for scientific excellence performed by Working Groups are perfunctory. We wish to stress that at present these Working Groups are composed of a plurality of non-government scientists who have the power to recommend initiation or rejection of new projects, changes of the workscope of existing contracts, increase or decrease of funding levels, and termination of contracts. In addition, the members are encouraged to suggest new areas for profitable investigation. The Virus Cancer Program has looked to Working Groups to perform these functions. The problems which the Committee has associated with present review practice will be eliminated by two actions of the Chairman, Virus Cancer Program. These include: (1) the chartering of an advisory committee composed of non-program scientists to provide broad directions on allocation of resources, areas for expansion of research and development of new leads and opportunities, and the application of research findings to the control of cancer in man; (2) the chartering of a Virus Cancer Program Scientific Review Committee to review individual proposals for scientific excellence and technical competence. The group will consist of 60 members, both government and non-government scientists, selected on the basis of their outstanding individual qualifications and recognized expertise in the fields of microbiology, molecular biology, immunology, biochemistry, and virology as they relate to cancer. A quorum of eight members, more than one-half of whom are outside NIH must be present at each meeting to review proposals. No member will be present during the portion of a meeting where a proposal from his own institution is being considered.

## RESPONSE TO THE RECOMMENDATIONS OF THE VIRUS CANCER PROGRAM REVIEW COMMITTEE REPORT

In essence, the recommendations of the Committee call for the establishment of a new approach by Government to fund the scientist at large. At present, the services and products necessary to accomplish the objectives of DHEW programs are obtained from in-house resources, through other Government agencies, under a grant, or by contract. The Virus Cancer Program was initiated by the Government under a mandate to the National Cancer Institute by the Congress to determine whether viruses were etiologically involved in human cancer and to develop some means for prevention or control of such cancers. Since the grant is an agreement by the Government to support the exploration of health-related research of the investigator's own choice, whereas the contract is the instrument whereby research and materiel specified by the Government is procured, the Virus Cancer Program has authority to pursue its objectives only by contracting with non-government institutions, not with individual scientists. The recommendations by the Committee overlook the legal obligations of Government and contractor as parties in a contract and center on an approach to an integrated program of research directed by non-governmental scientists at large. Either a new device to support investigators is required or one may seriously question whether the grants program does not in large part already fulfill this need.

The contention of the Committee that the growth and management of the Virus Cancer Program from inside Government was a mistake neglects the fact that specific regulations govern contract procurement. In such operations, advisory groups and Government employees make recommendations regarding the Government's needs for specific research and the capability of an institution to fulfill those needs. However, it is the Institute Director, his designates, or higher authority, if required, that approves the initiation of contract proceedings, and the Contracting Officer who negotiates and awards the contract. Since contract procurement is initiated to provide material return to the Government, the Project Officer monitors technical performance by the Contractor, protects the Government's interests, and insures good relationships and fairness to the contractor. This is accomplished by visits to the contracting organization by the Project Officer and consultants to the Government, by regular reports made by the contractor, and by regular formal reviews by consultants on review groups. Thus, the opinions of specialists within and outside the Government contribute to decisions regarding each contract for research.

Operationally, the Virus Cancer Program always has been open to research proposals and the recommendations of non-government scientists actively engaged in virus-cancer research. Such recommendations not only impact at working levels and on the direction taken by Program, but directly influence decisions which are ultimately made by authorized Government personnel. The limitations on funds, manpower, and materiel obviously introduce constraints and require judgments by individuals responsible for administration of the Program with respect to the overall research effort.

Those features that the Committee suggest should be conserved are the backbone of any integrated activity. These include meetings by investigators involved in Program research, centralized resources for research needs, and service or developmental contracts. However, the contract instrument is not limited to activities of routine development but includes individual research, development or demonstration projects that frequently lie beyond the state of the art and entail procedures of great complexity and difficulty. Under these circumstances a contractor, no matter how carefully selected, may be unable to deliver the desired result. Moreover, the job of evaluating progress may be difficult. In such circumstances, the advice of experienced consultants on review bodies and of site visitors is necessary and is routinely requested by Program.

Virus Cancer Program administration has been developing plans for an advisory group of consultants to provide input as to the direction to be taken by Program, development and establishment of priorities for research project plans, and selection of sole source projects. These plans coincide in large part with similar recommendations made by the Committee, particularly with outside membership on this group, except that Government reserves the right to direct the assignment of its own personnel and requires adherence to regulations governing such group activity.

The purpose of an Office of Resources and Logistics within the Office of the Associate Director for Viral Oncology is to obtain those reagents routinely used in quantity within Viral Oncology and its collaborative Program at minimum expense to the Government. Therefore, first priority is given to requirements for projects funded through Viral Oncology to maximize progress. Reagents have been provided, to the degree possible, to scientists not within the Virus Cancer Program. It is not within the purview of the Office of Program Resources and Logistics to establish priorities for distribution of reagents to scientists at large nor to undertake general distribution of available reagents. The Committee Report carries the suggestion that the Virus Cancer Program be obligated to underwrite costs of materiel for non-Program research and to establish a review mechanism for distribution of reagents to the scientific public. This is clearly not feasible within the limits of available funds and staff positions.

The Report recommends restructure of the Working Groups into a facsimile of the study sections. At present a restructuring of these Groups is underway to meet OMB directives. Present membership includes non-government scientists from this country and abroad, and the composition of the review bodies recommended by the Committee does not conflict with the views of Program Administration.

CONCLUSIONS: The flavor of the Committee Report calls for better input regarding desirable research by contributions from a group of specialists who would provide new concepts, fresh vision, and a suitable climate within the Program to attract greater and more diverse scientific capability to virus cancer research in order that the opportunities for achievement by the Program be maximized. The general substance of the Report also indicates that elements of bias which may pervade the processes of project selection be eliminated by a reorganization of project review groups. A better delineation of the responsibilities of Segments of the overall Program was recommended. The importance of resources and adequate quality control was emphasized. Unfortunately, suggested improvement was based on total destruction and restructure of Program and not on constructive modifications which could be readily implemented. We feel that the Associate Director for Viral Oncology, working with an advisory group of consultants, could accommodate the constructive features of the report and retain the positive aspects of the Program without the necessity for an intervening dissolution which would seriously affect ongoing research and impede the acquisition of data necessary to attain Program goals.

## SPECIFIC RESPONSES TO RECOMMENDATIONS BY THE VIRUS CANCER PROGRAM REVIEW COMMITTEE

### General

1. General Introduction: The recommendations of the Virus Cancer Program Review Committee suggest that the scientific community should be responsible for and totally direct the obligation of government contract funds. We call your attention to the fact that the legal aspects of such action require investigation.

2. Recommendations 1, 2, 3: The committee recognizes that the Program is already carrying out these recommendations. We intend to continue operating in this collaborative spirit.

### Intramural Program

1. Steering Committee: The Chairman, Virus Cancer Program, has already taken steps to charter a committee composed of outside scientists to advise on the direction taken by the Program.

2. Program Resources and Logistics: The Office of Program Resources and Logistics will seek expert advice on reagent production and quality control.

3. In-House Operations: This is an Institute problem now being rectified.

### Extramural Program

1. Chairmanship of Working Groups: The major issue in recommendation 4 is the suggestion that the National Cancer Institute recruit five or more Segment Chairmen from the outside scientific community as salaried employees to replace present Chairmen. The Committee should recognize that the Chairman's position requires full-time effort and attention to many details other

than chairing Working Group sessions. Little would be achieved by making a non-government scientist into a government science manager.

2. Composition and Responsibilities of the Working Group: The features presented in recommendations 5, 6, 7 and 8 are in practice. Members of Working Groups are approved by the Director, National Cancer Institute.

3. Termination of Current Projects and Readvertising: While we recognize that recommendations 9 and 10 are intended to provide opportunity for greater numbers of scientists to participate in the Virus Cancer Program, we question the necessity for complete dissolution of all on-going research. This would have a stultifying effect on progress. We are applying a selective process to maintain the best research bearing on the virus-cancer problem. See Tables 1a, 1b, 2a and 2b in APPENDIX B.

4. Technical Merit Review Process: The suggestions made in recommendation 11 are already in practice.

5. Presentation to Reviewers of Progress by Principal Investigators: Working Groups have requested the opportunity to confront the Principal Investigator to better evaluate progress and techniques and to provide suggestions when necessary. If this policy is to be discontinued, it should be upon recommendation by the Working Groups.

6. Finally, we agree with the Committee that format should not stand in the way of progress.

APPENDIX A

## REVIEW OF COMMENTS ON VCP*

| Member | Segment | Generally Favorable | Generally Unfavorable |
|---|---|---|---|
| Dales | DR | X | |
| Krim | DR | X | |
| Gallo | DR | X | |
| Hurwitz | STV | | X |
| Bloom | I-E | | X |
| Black | TVD | X | |
| August | TVD | X | |
| Gilden | BCV | X | |

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*At meeting of June 8, 1973, New York, ad hoc Review Committee members interviewed 8 of 49 outside members of working groups in the VCP.

APPENDIX B

## Table 1a

### PROPOSALS SOLICITED* AND FUNDED

| Period | Number |
|---|---|
| July 1972 - June 1973 | 3 |
| July 1973 - January 1974 | 5 |
| January 1974 - July 1975 | 11** |

* By advertisement
** Projected

## Table 1b

### PROPOSALS UNSOLICITED AND FUNDED

| Period | Number | |
|---|---|---|
| | Received | Funded or to be Funded |
| July 1971 - January 1974 | 149 | 22 |

## Table 2a

### VCP CONTRACTS

Major Modifications for FY 72 and 73

| Action | No. of Contracts | Reason |
|---|---|---|
| Termination | 36 | Low Priority |
| Reduction in Funding | 14 | " |
| New Contract | 44 | High Priority |
| Increase in Funding | 21 | " |

## Table 2b

### VCP CONTRACTS*

| Action | Number |
|---|---|
| Initiation (New) | 71 |
| Termination | 33 |

*Covers period July 1970 through January 1974
(FY 71, 72, 73 and first half of 74)

BOARD MEETING

March 19, 1974

Zinder: Since the meeting of January 1974, it was not possible to have a meeting of the full committee. However, its members stand on the previous document. Is more comment desired?

Rhodes: It would be useful to put this into focus again for the Board. Some members thought a new version would be forthcoming.

Zinder: I can make a few comments. When asked to review the VCP, I was skeptical of the National Cancer Plan, having had an opportunity to read the Thomas report. There are dangers in promises to the public and Congress. Overplanning creates the danger of dislocations in the biomedical community. The reviewers of the VCP were looking at only one segment of the Program without knowledge of other segments in the Program.

The document submitted lists the more formal meetings but not the telephone calls and letters which prompted synthesis of the report. The committee stands on the existing document. The document is divided into two areas, analysis and recommendations.

Viral cancer research is of high priority. It is also a model for study of the oncogenic process. In the review of the VCP, it became clear that high productivity in research of broad scope was not possible under the control of a small group of individuals. The result has been tension and antipathy in the scientific community. I assure the Board that it does exist.

On resources, I got unfavorable reports in private. In discussions with members of Working Groups, we got the feeling of dissatisfaction with the review process. Since the meeting, some members of Working Groups are more at ease. Huebner, Todaro, and Manaker are in-house managers and are also Project Officers on contracts. The Segment Chairmen are very powerful--. Dr. Price rated 50 percent of contracts at 3 or better.

The Committee report is in general terms with no evidence in the real sense. This was a review, not an investigating, committee. The letters received are not included in the report, which is a public document. The external correspondence was forwarded to Dr. Rhodes. Names are only for internal review.

There was some sentiment in the committee to restrict the VCP to services, removing fundamental research aspects to grants. On reflection the advantage of a viral oncology program was seen, if it were on a competitive basis. There is no reason for VCP support only by contract. Decisions on support are made by a small group in-house. Suppose a papovavirus were found to be the first human cancer virus. The VCP is not supporting papovavirus research. The EB virus produced was found useless by investigators supplied.

The Committee recommends: (1) Establishment of a "Steering Committee" to reorganize the VCP and advise. (2) Review of all contracts as a re-initiation, not a renewal. All contractors should be so notified. If the contractor has the expertise, there should be no trouble in recompeting. The VCP could fund several times the number of projects now funded. New concepts would trickle into the Program. (3) Local contractors should not do intramural work. The Committee favors support for intramural program, but within the NCI. (4) A program of grants and contracts is visualized overseen by the "Steering Committee". (5) Resources should be given on the basis of scientific merit, not on membership in the VCP.

Dr. Darnell wishes to make a statement.

Rhodes: Thanks for a difficult job.

Darnell: I wish to make some remarks on how the VCP could be broadened. I had no wish to make a comment, but Dr. Zinder wanted some support. I hope to give an outline as to how the program could be broadened. Two panels see applications for support, I serve on the American Cancer Society Panel and the NCI has a Virus Study Section in Grants. Awareness is creeping in that not all the answers are on hand of the connection between viruses and cancer much less human cancer. If there is no longer the case that there is need for applied research, there is more need for thinkers at the fundamental level.

At present, of 153 applications approved by the Virus Study Section, 68 were paid. So there are 75 added virologists in the country whose projects have been approved although they are without money. This would require $2 to $3 million dollars a year and would boost basic virology. In the last 1 1/2 years, the American Cancer Society saw 215 grant applications of which 180 were approved, but only 55 paid. These are similar to those seen by the NIH Virus Study Section. Five million dollars a year would have added 10 to 20 of these investigators to Program. These are highly meritorious grants. So there are many scientists in the community who could add to the VCP. A score of 160 to 170 will be the cut-off point for the American Cancer Society.

Rhodes: Are there questions? I would like to make some understandings (of what has been presented): (a) Money, which might have been saved, was expended too soon or too fast because of lack of understanding (of the complexity of the problem), or (b) There were opportunities to spend the money in the grants program. (c) There exists a lack of understanding to direct a targeted Program.

Zinder: We need a broader base of understanding in viral oncology - a less directed way of spending to get basic input.

Rhodes: Have we lost time?

Zinder: We can't ever be sure. In science, one doesn't know when one will get an answer. Some promising scientists are not being funded today. Had they been, one doesn't know if anything would have come out.

Schmidt: I want to get straight what Dr. Zinder recommends: (a) Would continue the VCP; (b) Wouldn't spend as much money as is spent today; (c) Would bring in outsiders as advisors from Study Section and ACS panel; (d) Contractors would supply support; (e) Bulk of the research would be by grants with maybe some contract research; (f) In contracts and grants, peer review by the same scientific cadre that would overlook the Program as a whole.

Zinder: As far as research goes, there is little difference between contract and grant. This hasn't a thing to do with what should be funded. The specified target of a contract does not fit a basic endeavor.

Schmidt: Those giving and receiving contracts say that they are not constrained. You say that at the current state of knowledge, this can't be specified.

Rhodes: I wish to call on Dr. Rauscher to comment on changes that have been initiated.

Rauscher: I wish to thank Dr. Zinder and the members of the Committee.

To put the situation into perspective, the VCP began in 1965 to have a hard-hitting program and to encourage young people to enter cancer research. Congress gave a highly visible amount of money to encourage bright people to come in. Contracts were selected as the funding mechanism because, at the time, grants had money, and contracts speeded up the funding process to 3 to 3 1/2 months whereas grant support required 6 or more months.

There was deliberate policy to get the best people to serve on review committees. Now that the field has become popular and money large, steps must be taken to separate management from review. We are going more into the program grant mechanism. There are best effort contracts with academic institutions. These could be converted to Program Grants with information made available to Program managers.

The policy in 1965 was to encourage investigators to enter the field. If basic or fundamental research was required to get from point A to point B, this would be done by a contract. It was thought to be unwise to use grants because these were investigator-initiated. Now - if we have a definable informational void, the program grant mechanism could be used. Also, funds for project grants are being increased. I will close by saying that things discussed yesterday at the Board meeting and Dr. Zinder's idea of changing the review mechanism - in general, the separation of management from review - will go a long way in satisfying Dr. Zinder's concerns. Present operations are inherited from the original deliberate organization at the beginning of the VCP.

Shubik: Had I heard the reports by Dr. Zinder and Dr. Darnell given today, I would hot have been as irritated as I was when I read the report. Today's comments are to the point and I would like to see them incorporated in the report. Today's comments are somewhat at variance with the substance of the report.

Rhodes: I would like a copy of the remarks to add to the report. After talking to Dr. Rauscher and others, I wish to take two steps: (1) To receive the report with thanks. (2) Appoint a sub-committee of the Board to follow its implementation and report to the Board to follow its implementation and report to the Board how rapidly this is being accomplished. Dr. Amos is designated as Chairman with Drs. Seitz, London, and Skipper as members. I would like the reaction of the Board to this proposal. I want to be sure this report doesn't fall between the cracks.

The material sent me by Dr. Zinder was not circulated because it is too personal. This will be given to the four people on the sub-committee. It bears out the stand of the Zinder Committee. I personally had the impression that the criticisms were by people I respect.

Charge to the sub-committee: Follow the implementation of the recommendations in the report by exchanges with Dr. Rauscher and his designates as to how NCI is taking advantage of the recommendations. I ask the sub-committee to report to the Board at every or every other meeting on this implementation, and if it can't be implemented, what considerations apply.

Watson: I wish to make some comments. I don't think the program is getting enough money. It would be a tragedy if the amount of money were decreased. Maybe (NCI) had been overly optimistic. But this program represents the best method for getting at the etiology of cancer.

In the Virology Study Section, the amount of money was too small. The VCP could think bigger with more money for a more limited approach. This created bad feelings by the failure of the VCP to recognize the breadth of the field and putting too much into the RNA viruses.

Concerning grants and contracts, I can't help but be disallusioned regarding the results of Study Sections. In VCP, outsider's input had not been recognized. I believe more mone should be requested and used fast. There is no long term hatred that would last five minutes. People just haven't gotten together.

The report is intelligent; perhaps one-sided. The main thing is that how viruses cause cancer is a complex problem. Virology Study Sections think small. I think a lot more money should be gotten into it, and the power should be diffused to get away from individual decisions.

Rhodes: I wish to quote: "Consistency is something with which great minds have nothing to to".

Amos: The sub-committee will phase its activity over the next year. Accomplishment cannot be done at one blow. Progress reports will be brought to the Board in an organized manner over time.

Owen to Amos: Give attention to the values in the ongoing VCP. It has been criticized, but it includes very able men with dedication to Program. It would be unfortunate if action were taken to disrupt this. I think many of us are concerned over stresses with which intramural workers have had to cope. I agree with Dr. Zinder on the support of a strong intramural program. A great many of us would have regret were severe damage done to a Program which has been a source of pride.

Amos: Dr. Zinder has given us a refreshing approach to new direction without saying that what has been done is bad.

Schmidt: It is fortunate that the Zinder Committee gave as much constructive input as it did.

Amos: The sub-committee is charged to bring the Board information as to wh is being done.

Schmidt: Zinder said to get good peer review, separate outside program management from internal management. The Board has said it shares that view. Dr. Rauscher is to implement this. The Amos Committee is to consult with Dr. Rauscher to see how implementation is done or that it is deficient.

Amos: Since we have different views of the function of the sub-committee, I hope we reach the same objective.

Seitz: All of us in the physical sciences can see how much was lost by too much concentration in a specific direction. We may get to a point where basic research people will say we can set our sights.

Senator KENNEDY. We will next hear from a panel of witnesses, consisting of the distinguished members of the President's Cancer Panel, Mr. Benno Schmidt, chairman of the panel and chairman of the board of Memorial Hospital, vice chairman of the Memorial Sloan Kettering Cancer Center, both in New York City, accompanied by Dr. Ray D. Owens, Department of Biology, California Institute of Technology. Dr. Owens is technical advisor to the United Nations Scientific Committee on the Effects of Atomic Radiation; and Dr. R. Lee Clark, University of Texas System Cancer Center, Texas Medical Center, who is director at large of the board of directors of the American Cancer Society, and president of the Scientific Committee.

## STATEMENT OF BENNO SCHMIDT, CHAIRMAN, PRESIDENT'S CANCER PANEL; ACCOMPANIED BY DR. RAY D. OWENS, DEPARTMENT OF BIOLOGY, CALIFORNIA INSTITUTE OF TECHNOLOGY, PASADENA, CALIF., AND DR. R. LEE CLARK, UNIVERSITY OF TEXAS SYSTEM CANCER CENTER, TEXAS MEDICAL CENTER

Mr. SCHMIDT. Thank you, Mr. Chairman. We are pleased to be here.

Senator KENNEDY. Gentlemen, we have benefited many times from your testimony and we are anxious to take advantage of your scientific and technical know-how.

Mr. SCHMIDT. Mr. Chairman and members of the subcommittee, I am going to keep my opening remarks very brief so that we can get to the question of the members of your committee.

I would like to say it is a pleasure for me and my colleagues on the President's Cancer Panel, Dr. Lee Clark and Dr. Ray Owen, to appear before your committee on the second anniversary of the passage of the National Cancer Act. The past 2 years have been very eventful years in the evolution of the cancer program, and there is no question that great progress has been made in that period.

As recently as 1970, cancer research was relatively on the back burner so far as our national priorities were concerned. In 1970, the Federal Government spent $180 million on its cancer research program. In 1971, while the Cancer Act was under discussion in the Congress, these expenditures were increased to $232 million.

In 1972, the first year after the passage of the Act, the National Cancer Institute was provided $378 million. In 1973, the amount was $432 million, and in the current fiscal year of 1974, expenditures will be $589 million. This latter figure includes $59 million which has been released from funds previously impounded.

During this period of very rapid growth in the Federal cancer program, it is my belief that a good balance has been maintained between grant-supported activities and contract-supported activities, between research aimed primarily at extending our fundamental knowledge of cancer and that aimed primarily at improving the technology of clinical care, and between extramural activities conducted in research institutions throughout the country and intramural activities conducted by the NCI itself.

I think these balances are reflected in the 1974 figures.

Of the 1974 budget of $589 million, $218 million will be spent on research grants; $95 million will be spent on research contracts; $81 million on supply and support contracts; fellowships and training grants will amount to $20 million; cancer control will receive $34 million; $51 million will be spent on construction; NCI intramural research will amount to $45 million; $18 million represents the NCI portion of the cost of the NIH clinical facilities, animal facilities, and the NIH management fund; the remaining $27 million is the cost of administering the program.

Intramural research at the National Cancer Institute has grown much more slowly than the rate of growth for the program as a whole, but this is in accordance with the policies of the director supported by the board and the panel.

In my opinion, there is absolutely no question that there is more and better cancer research going on today than has ever been the case in the past. Progress in some areas of basic science has been more rapid than was thought possible even 2 years ago.

Furthermore, as a result of the progress that has been made in the centers program, in the control program, in the task force programs, in the cooperative clinical groups, and in certain of the educational programs, we are seeing better patient care throughout the country for cancer patients today than ever before existed. As these programs realize their full impact, the benefits of this acceleration will be increasingly clear. We are beginning to achieve greater uniformity in the delivery of optimum care for such cancers as leukemia and certain other childhood cancers, for Hodgkin's disease, and for other rapidly growing lymphomas.

All of these cancers appear to be susceptible to restoration in the patient of a full life expectancy in a high percentage of the cases where early diagnosis is accompanied by aggressive treatment. Programs are also underway to improve both early detection and treatment in breast cancer, cervical cancer, lung cancer, and colon cancer, and other types of cancer are under intensive study by organ site task forces to achieve a formulation of the best technology available to us today as well as to conduct the best possible research on new insights.

Of course, not all aspects of the program have gone as we would like.

One of my disappointments as chairman of the panel was the discontinuance of the training grant and fellowship program. Although OMB was under very real and justified pressure to reduce the budget in a period of serious inflation, the decision to reduce it by cutting the training grant and fellowship program was, in my opinion, a serious mistake.

It is absolutely essential to our success that we bring our brightest young people into this program, and fellowships and training grants have proved to be the most effective and most economical way of doing that.

These are among the best dollars that we spend in terms of value received. The panel has done its best to present the arguments for this program, and we are disappointed by our inability thus far to get this program fully reinstated.

However, we are continuously pressing on this front. I am pleased that a $30 million fellowship program for NIH was announced earlier this fiscal year, and this program is scheduled to go to $60 million in 1975, and $90 million in 1976. This has enabled the NCI to restore its 1974 fellowship and training expenditures to $19,948,000 which is only $500,000 below our expenditures on these programs in our peak year of 1972.

Unfortunately, the restoration is not nearly so complete in such Institutes as General Medical Sciences, Allergy and Infectious Diseases, and others where the largest part of the training and fellowship program was funded. The training of these scientists is of utmost importance to all biomedical research, cancer as well as other areas.

In my judgment, when we look at the cost of medical care in this country today, we cannot afford to economize on the effort to produce the people who will make the discoveries that will facilitate prevention or simplify cure.

We have also been deeply concerned about the cuts which have occurred in the research budgets of General Medical Sciences, Allergy and Infectious Diseases, Arthritis and Metabolic Diseases, and the other Institutes. Neither the cancer program nor biomedical research in general can thrive if these Institutions are not healthy.

At the time we were urging on the Congress and the administration a greater effort in cancer, we were very explicit in the position that the increased cancer effort should not be at the expense of other biomedical research.

I am not sure that the cancer effort has been the cause of these other Institutes receiving less, but it is difficult to prove the contrary when the cuts have in fact taken place.

Also, regardless of what would have been the case in other circumstances, the fact is that this country cannot afford to reduce the research efforts of these other Institutes at this time.

Therefore, we have urged the Office of Management and Budget to give the highest priority to budget increases for these Institutes. I am hopeful that the budget for 1975 will include increased appropriations for these Institutes.

On the whole, the members of the panel and the members of the National Cancer Advisory Board, those who have been closest to the cancer program, feel that the program is progressing in a wholly proper and healthy fashion.

We feel that the director and his staff have done an outstanding job in administering the program during a period of intense growth while operating under highly restrictive personnel limitations. Enormous progress has been made, and great progress can be expected in the future.

However, cancer is an extremely complex and difficult group of diseases, and it is highly unlikely that we will have any single miracle of discovery that will provide an answer to all the cancer problems.

Also, cancer is long-range by its nature, and it takes substantial periods of time for the effect of carcinogens and other causative factors to manifest themselves and for the efficacy of treatment procedures to be determined.

Therefore, we must be patient and persevering and we must view this as a long term commitment by the administration, the Congress, and the American people. This is not to say that we will not make enormous progress as we go. I am convinced that we will. But I am also convinced that we will be working on some aspects of this problem for many years to come.

I would also like to emphasize that biomedical research has reached the stage today that there are no longer sharp dividing lines between the various diseases and research disciplines. Just as there will be important fallout to cancer from basic biomedical research aimed at other diseases, there will also be important fallout for other disease areas from the cancer research. This is already beginning to manifest itself in very important ways.

So far as the Cancer Act is concerned, it is my opinion that the compromises reached in the initial legislation have served us well, and that the present act provides a sound legislative foundation on which to build the best cancer program of which American science and American medicine is capable.

Whatever mistakes have been made have not, in my opinion, been the fault of the legislation. I see no reason why this legislation cannot serve us well in the future. I believe that the comparatively minor amendments that are embodied in the bill now pending before this committee are desirable amendments, and we of the panel recommend the continuation of the present legislation with these small amendments.

My colleagues and I will be happy to attempt to answer any questions you may have about either the proposed legislation or the program as it has thus far developed under the Cancer Act of 1971.

Thank you.

Senator KENNEDY. Well, thank you very much, Mr. Schmidt.

The members of this committee, and the co-sponsors and supporters of this legislation are very much in debt to the Panel for the suggestions you have made.

I cannot think of any Advisory Panel that has been more conscientious in fulfilling its responsibilities to achieve the goals of the 1971 legislation.

I think the recommendations that you have made and the amendments which have been proposed, and which we welcome, were made on the basis of some long hard thinking. Hopefully they can be translated legislatively into the kinds of improvements you desire.

One of your most interesting comments concerns the fact that along with the progress that has been made in direct cancer research, there has been a spinoff effect of great value to the other Institutes. In other words we have seen in this program, the broadest kind of communication and willingness to work with the other Institutes.

Mr. SCHMIDT. Oh, yes, there is no problem of communication on these kinds of things and even if the communication channels were not wide open within the National Institutes of Health they are wide open within the scientific community so that these things get moved about just as fast as the confidence in the discovery reaches the point that the scientist is willing to reveal it.

I can give you two examples without being able to be too specific about them.

In one of the Cancer Research Institutes where we are funding cancer research, there are very important discoveries today which appear to have more immediate significance and perhaps more immediate application to diabetes than they will have to cancer.

In the long run they will have some very important cancer implications, too; that is, if they are borne out. But they may have some very immediate implications so far as diabetes is concerned.

There are other discoveries that appear to have substantial importance so far as the understanding of multiple sclerosis is concerned.

These are simply examples of work that has immediate application and all work now in cell biology and molecular biology and cell surface phenomena, understanding of the immune system, immunology, and these fundamental research areas now pretty much transcend the boundaries so that the fundamental research in cancer is important in the overall picture just as the fundamental research in other areas is important to cancer.

Senator Kennedy. Your statement supports broader financial support for the other Institutes of Health as well.

Mr. Schmidt. Not only in my statement, Mr. Chairman, but a good bit of the time that I have spent with the Office of Management and Budget, and on my most recent appearance there I spent some time in emphasizing the necessity for stronger support for the other Institutes if the cancer program is to continue to be healthy and equally important and a part of the same thing if our biomedical community as a whole is to continue to be healthy.

I am very hopeful that that will bear fruit and the recommendations that you will see in the next few days.

Senator Kennedy. You have been a strong supporter for full funding of this program, but I know from both your public and private statements that you are a firm believer in insisting that the other Institutes of Health are funded to the extent that they can meet their responsibilities. You deplore any suggestion that progress in cancer should be made at the expense of the other Institutes.

Mr. Schmidt. Well, I have taken that position publicly from the beginning, but I have not heretofore regarded it as my area of responsibility.

I did feel in the recent appearance that it was so apparent that certain of the Institutes were not receiving what I considered to be funding commensurate with their capabilities and the needs of their program and the needs of other health programs from the developments within those Institutes, that I did, even though I am Chairman of the Cancer Panel, I did take on the job along with others of trying to intercede with OMB as strongly as possible on behalf of those other Institutes.

Senator Kennedy. I suspect the committee will hear more on this issue. And we will include that in the hearing record.

Let me just ask you a few more questions, Mr. Schmidt.

The Secretary questioned the wisdom and viability of expanding the number of Centers. Could you state the position of the Panel on the matter?

Mr. SCHMIDT. Yes. I think there was perhaps some misunderstanding in the discussion this morning.

When we back a Center we do not build a Center out of the whole cloth with Federal funds and commit the Federal Government to the future support of that Center either in its research activities or in its medical care.

What we have done in the National Cancer Institute is to pick those spots where, as a result of local initiative, sometimes State and voluntary, sometimes voluntary only and in a few cases State only, but where local initiative has brought about a situation where there is excellence in both clinical care of cancer patients and basic cancer research. The NCI makes grants to those institutions principally in support of their research and usually with the same review for excellence as the review of other grants. I say "usually" because in some cases, the review is still a very capable and full review but is not accomplished in the same study system, but usually the basic research grants to Centers go through the same study section procedures.

Now, the National Cancer Institute could not limit the number of comprehensive cancer centers if it wanted to.

The private resources and State resources are available for that purpose and what we do at the National Cancer Institute is simply recognize certain institutions which have reached such a standard of excellence in both patient care and basic research in the field of cancer such as to be called in our opinion a comprehensive cancer center. We have no ongoing commitment to those institutions for their continued support at any given level any more than we have an ongoing commitment to a science professor at the Harvard Medical School who is doing research under a research grant.

I do feel that we have to be prudent in the amount of encouragement and the financial level of encouragement we give and the number of places we give that to, just as we have to be prudent in the amount of grant-supported research, because we must think in terms of future budgets and the ability to help support these institutions in the future.

We thought it would be best if the act simply authorized the Director now—the original act set up a target for the creation of 15 Centers, and that was a recommendation of the Congress and it was understandable because the Congress wanted to give the Institute a target to shoot for. Now that target is well underway toward having been achieved.

We will now simply recognize when and where the degree of excellence has been reached in clinical care and basic research to justify that recognition and support those Centers in their research grant applications to the extent those grant applications fare well in the study section or see review competition with the other grant applications.

I think it would be a mistake to say we want to achieve 30 Centers or 35 Centers in the act. Conversely, I think it would be a mistake to say we can have no more than 15 Centers or 18 Centers.

We would like to see as many places as possible where cancer patients can get the best care of which American medicine is capable and where the best quality, the highest order of excellence in cancer research and biomdedical research is being performed and that is all a Center means.

It would be fine for the country and fine for all of us interested in this and other diseases if the numbers should grow, but there are limits within which we can spend money to make them grow.

Now, the Secretary mentioned construction. We have never in any year spent more than $57 million, as I recall, on construction and the allocation to construction in this present budget which is the largest budget we have ever had, the allocation to construct in a $589 million budget which is fiscal 1974, is $50 million. So we are not letting the support of bricks and mortar get out of hand.

What we are doing is giving some construction support to people who have substantial facilities already in existence and where a small construction expenditure will provide vast returns in basic research in cancer or clinical care or a combination of the two.

Senator KENNEDY. And the provisions in this legislation provide the degree of flexibility that the panel sees as appropriate and necessary?

Mr. SCHMIDT. I think that is right and I am just speaking to the point of any limitation which I think would be a mistake or a target requirement.

Senator KENNEDY. And you do not consider the creation and support of these types of centers as essentially a Federal takeover of the cancer program?

Mr. SCHMIDT. No, obviously it is not.

Dr. Clark directs one of the largest centers in the world and as he will tell you we do not pay through the National Cancer Institute for the cost of the patient care at his Center at all.

We support the basic research efforts and the clinical research efforts where that support passes muster so far as seen review against the competition is concerned.

All the Center means is that somebody has achieved a degree of competence and excellence in patient care and basic research all combined in one spot which entitles them to that recognition and whether that is the University of Wisconsin, M.D. Anderson, or Children's Cancer Research Foundation in Boston, their applications have got to be as good as the ones at Harvard or the University of California or the University of Southern California to get funded.

Senator KENNEDY. Senator Schweiker has a question on this point and then I will have one other.

Senator SCHWEIKER. Thank you, Mr. Chairman.

I gather in hearing your answer that there is apparently some difference in concept or definition.

Here is the Secretary's statement of this morning in which he says, "the National Cancer Institute estimates that 18 Centers will provide outpatient care within a 60-mile range to approximately 45 percent of the U.S. population."

He says, "inpatient care within a 120-mile range can be provided to over 80 percent of the population. With this amount of population covered, these Centers can effectively carry out an essential mission of demonstrating the best methods of cancer treatment."

He goes on to say, "to support any more of these Centers would move the Federal Government dangerously close to a complete cancer base treatment responsibility."

Reading that and hearing your answer I gather what you are saying is there are two different kinds of centers.

Mr. SCHMIDT. My difference with that statement starts with the words "to support," because let us take an example. Suppose the University of Chicago had a hospital with clinical facilities dedicated completely to cancer care and had a research organization in basic research that compared in excellence with one anywhere in the world dedicated to cancer care and they chose to pull all that together and meet the attributes which the National Cancer Advisory Board had laid down for a comprehensive Center.

Now, if they come in for a grant application say for $5 million or for $2 million or for $500,000, that grant application will be measured along with all other grant applications on its merits.

Meanwhile, as a result of that unification of activity having taken place those residents of the Chicago area who utilize that facility will be likely to get the best in cancer care that is available under the present knowledge and present technology.

It does not worry me if the number of cancer centers increases. In fact it will be good for the American people and good for the program if they do, but it would worry me if the inference were correct that once we recognize one of these centers we assume a certain level of future commitment so that pretty soon our entire budget would go toward the support of these centers and that is not the way the Institute operates and works.

The inference of that fear in the Secretary's statement I think just indicates a little lack of feel and understanding about how the system works.

Incidentally, he is not alone in that. There have been a lot of people who have been worried that by the creation of these cancer Centers we were preempting the future research budget and that noncenter people would not be able to get funded. His statement I think is a reflection of that point of view which I am saying is a misunderstanding in relation to what the center does.

Senator SCHWEIKER. I think you have made it very clear.

What I understand you are saying is, just because you designate a Center that does not mean that any total dollar commitment or support level is guaranteed to that Center.

Mr. SCHMIDT. That is correct, and in general we do not support general patient care at any of these Centers that we have recognized.

We have given some of them—in an effort to meet the original legislative objective of 15—we have given some of them construction grants to help on clinical facilities as well as research facilities, but no commitment for the future.

Senator SCHWEIKER. On an individual basis along with all the other judgments you are making?

Mr. SCHMIDT. Every year.

Senator SCHWEIKER. Thank you, Mr. Chairman.

Senator KENNEDY. Senator Pell?

Senator Pell. Mr. Schmidt, you may have heard the exchange with Mr. Weinberger concerning international cancer data banks and my questioning of him.

Are you satisfied with the progress that is being made on the development of the cancer research data bank program, or not?

Mr. Schmidt. Well, the Institute is working I believe as hard and as effectively on that as they can.

We devoted an entire panel meeting about 2 months ago to a review of everything they are doing. I have learned something in the last 2 years and that is that it is a lot more difficult to put a lot of this information that you are talking about and that I was talking about 2½ or 3 years ago into common language so that you can get some simple answers out of a computer very rapidly and that is one of the great problems they are struggling with because if our research experiments bore numbers and they were all done alike you could ask what the results were that would be susceptible to very simple computer language.

But, when you get to all the variations and all the ramifications, getting this down to the simplicity that you would like to see and that I would like to see if it were possible becomes a much more difficult task.

I think we have extremely good data processing people who are devoting full time to this and I think a tremendous amount of progress has been made and I think all the progress that can reasonably be expected will be made.

I think Dr. Clark might like to amplify this, particularly so far as the International Commission is concerned.

Dr. Clark. I welcome the opportunity to present to you what we have done, because it happens to be at the appropriate time.

I was encouraged to proceed along this line for some 28 years in a major cancer institute.

One of the big problems has been in knowing what is current in research and therapy, what is being produced by other groups and institutions, and making this information readily available to our scientists. To achieve these goals, we have done three things very specifically since the National Cancer Act of 1971 was passed.

First of all, on the national scene, we have formed an association of cancer institutes. We are bringing in all the new cancer institutes to share the information we have acquired over the years prior to this act that would be useful to them, so that they can begin at the point of expertise where the older institutions are. There is no need for them to lose the time on a number of cancer-related activities when they can use the information already available.

One of those institutions that has been so extremely helpful in the past is Dr. Sidney Farber's institution (Children's Cancer Research Foundation, Boston). I want to do homage to him today, and I regret this is the first time I have testified here over the years without his presence and his encouragement. He has been great in science in an organizational way and in his unstinting effort to put the National Cancer Institute in a position where we could all benefit from the planning and knowledge that would emanate from the legislation that he encouraged.

I would hope his institution could proceed to become a national comprehensive cancer center and fulfill the dream he had for it under this legislation.

To return to my discussion about the plans of the Association of American Cancer Institutes we have now outlined 12 tasks for establishing cooperative activities and uniform practices for which we are sharing information with each other. We are proceeding under the direction of the National Cancer Institute to put these tasks together in documentary form, and to invite all directors of the new institutes and the directors of the older ones also to get together and to share their information.

We will have a Telex capability among us so we can have immediate exchange between libraries and for all types of information.

On the international level, the National Cancer Institute and AACI proposed to the International Union Against Cancer (UICC), which is a consortium of 76 nations in the world doing cancer work and was established on a nongovernmental basis, to share with us the development of an international cancer research data bank and to compile a directory of international cancer centers and institutes.

We have made great progress in these efforts under the direction of Dr. Gregory O'Conor and Dr. Frank Rauscher at the National Cancer Institute and will be able to deliver to a meeting in Geneva on May 25 the following accomplished facts:

(1) A preliminary directory of international cancer institutes and centers.

We ended up with 4,000 points of ingress to the international knowledge by simply going back to all the cancer literature that had been produced in the last 5 years, and finding where it originated.

We think we will end up with 300 or 400 centers in the world that are doing some cancer research. We will then try to share through these 76 UICC member-nations the information that is being generated from their countries. We will not duplicate existing repositories of data but simply mark where they are and define their capabilities for future use when we hopefully develop a common computer language for rapid information exchange.

In the end we will have a standardized means for end results reporting and classification of diseases, so we can have a common language in discussing all of our problems of research in relation to better cancer treatment.

All information about what is going on in any one phase of cancer will be available.

I recently visited Heidelberg, Germany, which has a new data processing center that is coordinating all the cancer research information in Germany.

In Paris they have joined together the 24 cancer centers in France. They meet on a quarterly basis and share information and common knowledge and funds. That information will be made available to the international data bank, too.

(2) An inventory of international cancer data sources or repositories will be delivered at the May meeting in Geneva, also.

We already have, as Dr. Rauscher told you, started the Dial Access, which has 267 specific questions and answers by telephonic communication to requesting physicians in 17 of the Southern States. It will reach 60,000 physicians.

On the first pilot trial of this system we had 3,000 inquiries in the first 10 months. We think that this will be very helpful, because it gives precise answers that are up-to-date from an expert in the field and a brief literature review.

Another area of international cancer research which is being conducted through the Committee on International Collaborative Activities of the UICC is the compilation of a directory of carcinogenic agents to increase the total knowledge of the very important field. Yesterday I met with Dr. McGovern, of the Board of Regents of the National Library of Medicine, in our own institution to discuss collaboration on making the cancer literature available for rapid recall.

This is very difficult, as Mr. Schmidt said, to develop a common computer language for recall of a comprehensive bibliography of a given subject in cancer.

We have at Anderson Hospital (University of Texas) a compilation of literature from many of the journals of the world that contain cancer-related material. We retrieve about 20,000 articles of clinical value per year, and we have been publishing and distributing this gratis for some years. This information well be turned over to the Library of Medicine to be put into the files so it can be recalled by regional libraries in any part of the United States, and that will be on trial by May.

Senator PELL. In other words, if some information is developed in Lyon, France, will this information be programed into the computer in the United States? Is it presently?

Dr. CLARK. It will be very simple to duplicate the tapes of either place, you know.

Senator PELL. Is it, or will it?

Dr. CLARK. It will be. The international data bank is now in the process of being formed. It is not yet completed.

Senator PELL. When do you expect, or hope, that there will be a depository in the sense we are talking about, an international depository?

Dr. CLARK. I would say in May these five points will be completed in their preliminary form and be made available for recall.

Senator PELL. May of 1974?

Dr. CLARK. Yes.

Senator PELL. Does this mean, so I know what we are talking about, that the results of the studies that are run in Germany and France are put into the bank, the data bank we have here, and a fellow in my city of Providence, R.I. can dial the telephone and ask the question to the computerized data bank?

Dr. CLARK. There will be an intermediary first on this, and it is going to get set up. We do not want to duplicate the repositories. We want to call on them, and it does become pertinent to the rapidity of retrieval if you have information duplicated and put into a computerized data bank in this country.

Senator PELL. Should there not be one repository where all cancer data is located? For example, you might want to know about an experiment that we run, and you do not want to query all the other centers in Europe as to whether or not they ran this experiment. It must be available quickly.

Dr. CLARK. Right now there is a repository for ongoing research, and it is at the Smithsonian, where you can request information on any subject that is being researched in a specific field and get an answer.

Senator PELL. We are beating around the bush, I think.

The Smithsonian uses four by six cards. When will this data be deposited in what we call a computer?

Dr. CLARK. This program is in the process of evolution, and it will take some decisions on the site or sites of the data bank or banks and regarding the immediacy of its capabilities for response. We do have a target date for the five things I mentioned.

Your all-encompassing complete information data bank would take some while longer to program and make available.

Senator PELL. What I am driving at, obviously, is to assess whether we are not going backwards in this area. I would hope you would go ahead, and what we are talking about here is the single depository.

Mr. Weinberger said bricks and mortar. I do not care if it is stone and steel, there should be a place where this information is on deposit.

I am not a systems training man, but I am very pleased with what they do, and I think what you are talking about is still little centers that you will have to query one by one.

Dr. CLARK. First of all, you have to get what is available; otherwise it will take a long time and duplication of effort.

From that stage we can see what is required for immediacy.

It is the matter of studying the priorities and needs of the scientific community. We have to assess the scientific needs from that data bank, and also the immediacy of recall. In other words, if I inquire tonight, do I need it tonight, or would it be all right if I had it in the morning?

These are things that are in the process of being decided, and I have been personally encouraged by the returns on this.

Senator PELL. But you say the process is being decided.

I believe that the law has already decided that we should go ahead and do this.

Dr. CLARK. I mean of the methods.

Mr. SCHMIDT. Senator Pell, we have hired some of the best data processing people we can find anywhere in the country, and we have borrowed some others, and they have been doing the best job they know how to do to carry out the mandate of the law.

Unfortunately, this information is not as neat, and as labeled, and as uniform as you would like it to be, and as it needs to be for computerization to have maximum effectiveness, so when your doctor in Providence calls up and asks a question, even if you have this computer, if he does not ask the question exactly like the man who put it in the computer said it, or asked it, then he will not get the answer back. And as I said earlier, these discoveries and experimentations do not take a uniform form.

Now, we can, and we are compiling a great deal of information that will be available in Providence, and available in Houston, and available in Paris, and if you ask the right questions, the answers will come out, but if a man is about to do an experiment that has just occurred to him and he wants to know whether that experiment was done or not, I doubt very much myself, and I am not expert in this field either, but I have gotten to know more about it than I did before this assignment came along, and I doubt very much if you will ever have the commonality of language and the capability of programing to anticipate questions that your doctor or my doctor or somebody else's doctor would ask about prospective research experimentation.

We know what the mandate of the law is, and we are going to come as close to carrying out the mandate of the law as current technology and reasonable resources make it possible to do.

Senator Pell. Let me make sure I understand what you are saying.

Are you saying that a laboratory might consider going into an experiment, and would not be able, even if this mandate was carried out, would still not be able to find out if this experiment had been carried out in Germany, or some other country?

I would disagree. My understanding was that this kind of question could be taken care of.

Mr. Schmidt. That kind of question will require a description of the proposed experiment in total detail, and unless the man who has programed the computer knew how to anticipate that program there is no way you can make a computer answer a question that has not been anticipated by the man who programed the computer.

We can answer the questions that our people are smart enough to anticipate, but we cannot answer the questions that have not been anticipated by the man who programed the computer.

Senator Pell. But if every experiment has been carried out, has been programed into the computer, then the result of the experiment can be asked?

Mr. Schmidt. But it has to be programed with a title and a word.

For example, we have been trying to get this computerization at the major centers themselves. That in itself is tough.

We have a program at Sloane Kettering today that if you ask a key word, no matter what it is, it can be the name of a drug, it will give you the listing of everything that is in our library that relates to that, but then if you punch the computer buttons that require all those answers you will get volumes of material out on that subject.

I think we have made considerable progress, and we can make more progress in the direction of this, but I do not think we will ever have it as neat and as nice as we would like to have it for the reasons that I have given you.

I just do not think you can anticipate all the programs and all the questions.

Senator Pell. But you do see an international data research bank as more than the label on the door and actually existing at some point?

Do we have that, as yet?

Mr. Schmidt. I do not know whether the label is on the door or not, but there is a place in the National Cancer Institute where this function is being performed.

Senator Pell. Under this label?

Mr. Schmidt. Under that label.

Senator Pell. I have two more very brief questions on the subject.

One, do you really mean, Mr. Schmidt, the optimism implicit in your statement that we are beginning to achieve greater uniformity in the delivery of optimum care for such cancers as leukemia and certain other childhood cancers, for Hodgkin's disease, and for other rapidly growing lymphomas?

All of these cancers appear to be susceptible to complete cure in a high percentage of the cases where early diagnosis is accompanied by aggressive treatment.

Mr. Schmidt. I think you will get different views from different clinicians about how high the percentage is, but there is pretty general agreement today that it is over 50 percent.

Senator Pell. For leukemia?

Mr. Schmidt. In childhood leukemia, if it is diagnosed at an early time and treated correctly from the beginning. and treated aggressively from the beginning.

Now, one of the problems is that we have only had these protocols that are producing these results—well, beginning 6 or 7 years ago and being improved all along. And so when you get a 5-year period with no symptoms and no indications of regression, you are hopeful that that is an indication of a complete cure.

You may find out 20 years from today that it was not an indication of a complete cure.

Senator Pell. Thank you.

My final question is, is it correct that cancer is not contagious—even though perhaps a virus?

Mr. Schmidt. I think that is the best information that exists today.

There have been a few little things that caused people to wonder about certain types in certain situations, but I think, in general, most of the clinicians and scientists who work in the field proceed on the assumption it is not contagious.

Senator Pell. Thank you.

Senator Kennedy. Senator Javits has some questions.

Senator Javits. You are satisfied, with regard to the manpower and personnel questions, that we will be able to get the 109 slots filled?

Mr. Schmidt. I think, as a result of the responses we have recently had, we will carry on the work of the National Cancer Institute satisfactorily with the additional places that we are being given.

We still have problems that are common to all the Government, that a lot of our top people have not had salary increases for several years.

I think there are about 70 people in the National Cancer Institute who make the same salary as the Director today because everybody is pushing against the ceiling, but that is a problem that is common to the Government.

There is one special problem, and that is a personnel problem that concerns us. It is a NIH problem specifically, but we still do not see a sufficient complement of nurses in the NIH Clinical Center to operate the Center at the levels that it should be operated at.

It seems to me that is a bad economy and we have made the point a number of times, and we will keep making it. But, apart from the nurse point, we have gotten pretty good satisfaction on our other specific personnel requirements so far as number of people are concerned.

Senator KENNEDY. Thank you very much, gentlemen.

Our next panel of witnesses are representatives from the Candlelighters of Washington, Mrs. Grace Monaco and Mr. Richard Sullivan.

Mrs. Monaco is associated with the firm of Wheatley and Miller.

Mr. Richard Sullivan is chief counsel to the House Committee on Public Works.

We welcome you both.

## STATEMENT OF RICHARD J. SULLIVAN AND GRACE A. MONACO, REPRESENTING THE CANDLELIGHTERS

Mr. SULLIVAN. Mr. Chairman and members of the committee, my name is Dick Sullivan, and with me is Grace Monaco.

With your permission, we would like to file the full statement for the record.

Senator KENNEDY. We will have it printed in the record at the conclusion of your testimony.

Mr. SULLIVAN. Mr. Chairman, you state we represent a group called the Candlelighters who are parents of children who do have or have had cancer.

At the present time, there are groups in 16 States, and in the ultimate sense we can say that we are the consumer here today.

The results of the research program is what kept our children alive for a certain period of time.

Through the continuation of this type of research program, we can eventually reach the solution we all desire. We are all extremely grateful to you, as chairman of this subcommittee, and your members, and your counterpart in the other body, Congressman Paul Rogers of Florida, for the lead you have taken in this important field.

There is nothing more important as far as we are concerned at this particular time than the welfare, well-being and the future of our children. As you know and I know and Mrs. Monaco knows, and the members of your committee know, this is one of the most insidious of all diseases. It hits children unexpectedly, and in many cases parents do not realize that cancer can hit their children.

It is the leading killer of children in the United States.

The 1971 Act that you gave to us as parents was indeed a fi Christmas present and once again, not to overdo the compliments, do commend you, both bodies of the Congress and the President the United States for writing this act into law.

We note the funding for that program was $1.5 billion over a year period of time. Unfortunately, like so many programs that t Congress has authorized, there has been a failure to fully fund t authorized figures.

There has been an up and down, a sliding scale, Mr. Chairma and the money has been, in some cases, impounded or, unfortunatel been caught in tangles of other labor and health and educati programs, and there have been several vetoes of this particular ty of legislation.

Research is a continuing process that must be carried on. It cann be done like a yo-yo jumping on a string up and down. And would strongly urge this committee of the U.S. Senate and the Hous of Representatives and the President himself to see to it that in th particular category we move steadily forward in the field of researc

We must move ahead with this thing. It has to be the ultima answer to what we all seek.

You are now considering a further amendment to the basic act 1971. We strongly support and urge a continuing funding of th program at a higher level.

We would respectfully suggest to you, from our experience, tha the figure be somewhere in the category of $2.7 billion over the next fiscal year periods, taking into consideration the increase in cost an the rising inflation that we are dealing with.

This is one of the points we wish to make about a continuin funding for the research program.

The second point we would like to throw in, too, briefly is th question of impoundments. You are all familiar with that in man fields. You are, sir, very much so.

We know what has happened in the water pollution field an other vital programs.

This question of impoundment must be stopped. There have bee successful suits in the lower District Courts which have required th executive to release these funds.

You have had legislation which has passed the Congress of th United States which clearly prohibits the impoundment of funds fo public health services, such as the legislation we are concerned wit today.

We would hope, in the final markup by your subcommittee, and eventually by the Full Committee, some sort of language which would prohibit the impoundment of these funds for this particular field would be contained in the legislation because of the vital necessity of what we are dealing with today.

In addition to this, Mr. Chairman, we have listened with a great deal of interest to the comments of Secretary Weinberger and Mr. Schmidt about the 15 cancer centers in the country. We naturally cannot speak to you from the technical expertise on health and education, but we can say to you from a very practical viewpoint, Ir. Chairman, that we need more than 15 centers for only one eason, because of the physical factor.

We know from our own experience from people across the country hat in many cases people have to go a day or more either for esearch or actual treatment. This is a hardship. It sometimes forces he family to move and can have an ultimate effect on the health and vell-being of the children being treated.

We would hope there would be an expansion of these 15 centers. Ve would propose to you a figure of 33 or, if not that, we would eave that to the discretion of the National Cancer Institute, but omewhere along the line we want to stress the need for and the esire to expand the centers beyond the existing 15 because their vork is vital to the continuing success, both from a research standoint and from a health standpoint of children who are being reated and whose lives depend on the legislation you are considering ow.

In addition to that, we are concerned about the fact that you very orrectly gave an independent status to the National Cancer Instiute so it cuts through the maze of red tape you deal with in overnment and allow them to report directly to the President of the Jnited States.

We hear disquieting rumors to the effect that in many cases, they re being handicapped by the National Institutes of Health or the ecretary of HEW.

I am familiar enough to know we are not too sure of this, but we vant to point out to you that you would reemphasize the independnce of the particular group.

I was happy to hear yesterday when I talked to the people down t the budget, and as you commented today, that these positions are eing released because these positions are vital and essential to the peration of the program.

It is nice to have money, but without the professional people to arry out the programs, what good is it?

This is another thing that was held up by some man downtown vho determined he knew what to do when the Congress had made a ecision about these positions.

Mr. Chairman, as we see our children treated, we know that the job is being done. We know that if it is to be done, it will be done at NIH, at Children's Hospital in Washington, D.C. and similar instiutions across the country by the doctors and the people in the field who keep this program going and give us hope.

Senator Pell has stressed and properly so in his comments both to Secretary Weinberger and Mr. Schmidt, Mr. Chairman, the need to develop an international data bank.

We respectfully suggest to you there is a need to develop a domestic data bank in this country, Mr. Chairman, and let me tell you why.

There is, we find, not in a critical sense now, in many cases, an appalling lack of knowledge in the field on what is a cancer.

In many cases, there is a misdiagnosis by a physician. Sometimes it takes two or three doctors before the ultimate diagnosis is made that the child has leukemia or has a solid tumor. Valuable time is lost which that child could be treated.

We propose to you a domestic data bank, Mr. Chairman, to corr late the information across the country, tie it in so that doctors, t medical people, the researchers, will know what is going on, and t parents themselves will have a better knowledge and understandin of what the program is and have more confidence and more suppo when they feel their child is getting the best treatment possib under these circumstances.

There is no more difficult period for a parent, Mr. Chairman, tha that moment when the doctor comes to you and tells you your chil has cancer and the possibilities are that he has 1 year or 18 months 2 years to go; it is helpful if they can also be told that all right, th diagnosis and expectancy may be true, but somewhere down the lin hope may exist, and the best possible information is going to be mad available to realize that hope.

Under those circumstances, we think there should be a domesti data bank. I do not say this in an emotional sense. I say this in very practical sense, that we figure there is a need, a crying need, t take a long look at creating a domestic data bank, and there woul be no better place for it than the National Cancer Institute itself.

I may be talking a little too long, but I would like to make on final point.

There is a need to continue and expand the fellowship program We know from practical operation in Children's Hospital here tha these young doctors, who are coming in to research and treat ou children, depend on the subsidies they are getting from the fellow ships. These doctors are acquiring the background and trainin through this program to eventually become the experts.

We would like to conclude by thanking you for the opportunity t be with you today. We think the committee has done an excellent job We think the President has done an excellent job, the Secretary, and everyone else.

We are simply here to say and stress the vital need of and urgency for the research program to continue.

We think the supportive clause should be in there and hope and pray that you will come out with a strong bill and get unanimous support.

I thank you for the time of the committee.

Senator KENNEDY. Thank you.

[The prepared statement of Mr. Sullivan follows:]

# STATEMENT OF THE CANDLELIGHTERS

Before the

Subcommittee on Health

Senate Committee on Labor and Public Welfare

January 30, 1974

We represent the Candlelighters, a group of Washington area arents whose children have - or had - cancer. There are similar roups in 16 states. My name is Richard J. Sullivan, and with me s Mrs. Grace Anne Monoco. One of the chief aims of our group is o improve federal cancer research programs. We know that the lives f our own children have been extended and, in some cases, saved hrough cancer research efforts funded primarily by the federal gov- rnment. In the ultimate sense, we speak for the consumers of can- er research. Since our children's lives depend upon cancer research e have become sensitive to deficiencies in the program as well as he needs to expand it.

Under the leadership of this Committee, and particularly of the istinguished Chairman, Senator Kennedy, as well as his colleague in he other body, Mr. Rogers, the Congress enacted the National Cancer ct of 1971 which the President signed into law on December 23, 1971. his "war on cancer" was a Christmas gift to the nation and all of us re profoundly grateful to you, to the Congress and the Chief Executive or this initiative in an area that touches the lives of every American amily. As is true for all initiatives, this one, too, has had some of ts bright hopes unrealized, and we wish to discuss some of these de- iciencies in this testimony and perhaps suggest some improvements.

The first and foremost item which we wish to raise for the consideration of the Committee is resources. The National Cancer Act of 1971 authorized appropriations of $400 million for FY 1972, $500 million for FY 1973,and $600 million for FY 1974. The actual amounts appropriated fell far short of this goal principally because the President requested less, and repeatedly vetoed appropriations which came close to the authorized amounts. Added to the problem raised by these lesser amounts was the impoundment of funds which aggravated an already tight situation with respect to research, and which has seriously retarded the national cancer program. It must be clear to anyone that cancer research is not something that can be turned on and off. Impoundment has without a doubt a very long negative effect on the progress of the research projects. Our children profited from the cancer research investment made in years gone by, but the loss of momentum resulting from underfunding or impoundment will seriously affect the millions of Americans who will develop cancer in the years ahead, as well as those presently suffering from the disease. The Administration has compounded the funding problems related to research by impounding positions as well as actual resources. It was only a public outcry which caused the Office of Management and Budget to release 107 positions for the National Cancer Institute required not only for research projects but also for the cancer treatment, itself.

The $1.5 billion which you authorized in PL 92-218 did materialize in lesser amounts, and then only grudgingly. The 60 million impounded from the FY 1974 has allegedly now been released under conditions which make it questionable that the maximum research yield will be obtained promptly. We find it very difficult to obtain adequate information on funding and we hope that this Committee will press the Administration with vigor to determine whether or not the FY 1974 appropriations have already been released.

Despite the budget shortfalls, and despite the impoundment and despite the bureaucratic harassment, the National Cancer Act of 1971 has been a good and wise investment in the wellbeing of our country and our people.

We sincerely believe that real and concrete strides have been made which have benefited our children. We must not stop or falter. The legislation must be extended. In terms of resources, we would propose to Congress to authorize $2.7 billion for the next three-year period. We would further propose that the language presently contained in Section 601 of Public Law 91-296 forbidding the Chief Executive to impound public health funds should be carried into the new legislation, and meanwhile this provision should be extended beyond the June 30 expiration date. We feel that $2.7 billion divided over a three-year period is a realistic amount, given the base of the first three-year period and the high rate of inflation which has lessened the value of the amounts initially proposed in the 1971 Act.

We further ask that the limit of 15 national cancer research centers be stricken, and that the legislation leave the number to the discretion of the Director of the National Cancer Institute. If this is not possible, we would ask that the number be raised to 33. We know from our own groups around the country of the hardship it places on many patients to drive very long distances for the frequent treatments necessary to abate the course of the disease. Unless such centers are within a one day's drive for a patient, it will place out of reach the absolutely essential elements of treatment for a very large number of Americans who are so affected. We must enable the largest number of Americans possible to benefit from cancer research. A larger number of centers are essential for this purpose.

We have alluded earlier in this testimony to the impoundment of positions. This is a very serious matter. Obviously additional resources cannot be effectively utilized if personnel positions remain frozen. Provision should be made in the legislation to free the Director of the National Cancer Institute from the bureaucratic restrictions placed upon them by the NIH and the Department of Health, Education and Welfare. It does not seem very logical to promise the American people a cancer control program and then not allow positions to be filled. We could tell some horror stories of cancer wards at NCI remaining empty because of lack of personnel, and laminar flow rooms, which could have prolonged a child's life, being un-utilized because of positions which could not be filled. We must not permit some faceless bureaucrat to superimpose his judgment on personnel over those of the Director of the National Cancer Institute.

We also believe that separate provisions should be made in the new Act for the funding of a cancer information clearing house which would provide to the physicians and the public current information on cancer treatment.

We hear from our members all too many stories of misdiagnosis and is-information which has caused needless suffering and frequently has revented timely and adequate treatment for this disease. There is a remendous gap between what could be done for the cancer patients and he care that individual physicians are delivering. The following xample might illustrate the point: children who have leukemia must ndergo periodic bone marrow tests, a very painful procedure where a eedle is inserted into the hip bone and the marrow is extracted in earch of the leukemic cells. Some of the Florida Candlelighters told s of a new method whereby the parent can attach an anesthetic bandage o the hip three hours prior to the insertion of the needle, which reieves the patient of most of the pain.

We informed the NCI and, finally after a considerable period of rging, the NCI has now adopted this method of preparing the patient for bone marrow test. The pain and suffering which could be avoided by he dissemination of just this little piece of information alone would ake the insertion into the Act of a provision for the cancer informaion clearing house very worthwhile.

The present language of the Act, for an international research ata bank, deals only with research, and we need to do so much more ith respect to treatment, particularly information to the family hysician or pediatrician who is usually the first doctor contacted ith respect to the disease.

The family physician needs a central information center which an give him the most comprehensive and specific information on the treatment of each specific cancer problem that he may encounter. Such information will also permit the parents of the stricken children and older cancer patients to cooperate completely with the physician in charge of their child or relative's treatment to provide the proper nutrition and supportive environment for the optimum success of the treatment program.

The knowledge in the data bank must constantly be updated and changed; and it seems to us that only the NCI itself can do this task. Cancer victims, their families, the parents of children suffering from the disease, should have the peace of mind that the treatment which is being given is the most up-to-date, and is the best that can be provided. We strongly feel that this is presently not the case, and it would be a wise investment to create a cancer treatment information center.

In the past few years, we have received many questions concerning nutrition, both from our Washington membership and from other parents around the country. We have learned that there are some isolated research projects in this area being carried out in various parts of the country supported by NCI funds. However, there is no coordinated nutrition effort at this time. With so many foods and food additives being declared carcinogenic by the FDA, it is very confusing for the average housewife to know what she should or should not feed her family. Furthermore, when you have a cancer patient on a sophisticated drug regimen, this problem is greatly compounded. Thus, an enlargement of the research effort in this area and a coordination and dissemination of the results of these efforts through the public data bank we have just discussed is greatly needed.

We hear again and again of the interference by the Department of Health, Education and Welfare and by OMB in the work of the National Cancer Institute. Despite the language presently in the Act, HEW regulations require that the head of the Cancer Institute must clear any public statements with HEW. We believe this to be totally wrong. The American public has every right to hear directly from the head of the NCI without clearances from the HEW hierarchy.

We further believe that OMB, HEW and NIH have illegally interfered in the allocation of positions and resources to the NCI, and feel that there should be new language in the extension of the law to prevent such interference in the future.

In the past three years, the bureaucratic interferences have negated specific authorization and appropriations for such items as training programs. The will of the Congress has been expressed by means of authorizations and appropriations, and the executive-branch must be made to obey its constitutional mandate to faithfully execute the law. We leave it to the Committee to find the means of doing so.

Mr. Chairman, we are grateful to you and to the Committee for permitting us to appear before you. We want you to know that cancer research has been effective, not as effective as we would have hoped it would be, but, nevertheless, strides have been made and the lives of our children, in many cases, have been prolonged, and for this we are grateful.

The recommendations that we have made are intended to strengthen the program. Our criticism was not meant in any derogatory sense, but is evidence of our desire to overcome the deficiencies which we have found. The war against cancer will not be won easily and cheaply. An advance has been made. We ask you to extend the Act for a second stage, during which we hope that the progress will be more rapid.

Thank you.

Senator Kennedy. Mrs. Monaco?

Mrs. Monaco. The only points I make in supplementing M Sullivan relate to the data bank and to the point made with respe to the need for increased research in the area of nutrition.

Fortunately, the founding member of our South Florida Candl lighters has a husband who is a medical librarian. As a result of thi sometimes we find out things before some of the doctors are eve aware of them.

For example, about 2 years ago, our South Florida chapter fo warded to us the information that there was an anesthetic patc available that could be placed on the spot where a lumbar punctu or a bone marrow would be done on a child a few hours before it wa done, and this would remove a great deal of the pain and the resulta fear associated with this type of treatment.

Some of these children have to undergo a number of lumba punctures in order to get the drugs introduced into the system to ki the infiltrating cancer cells.

Due to the work of parents' groups exerting pressure on th Clinical Center at the National Institutes of Health and bringin the knowledge to their attention that one parent's group had give to another, the National Institutes of Health, at their Centers, now are using this lumber puncture anaesthetic device.

This is the type of information that we hope would be availabl through a data bank that our family physicians, our treating physicians and the public themselves, particularly the parents who ar involved and want to play a strong supportive role in the treatmen of their children, would be able to have access to. Because with thi type of information, we can ease the pain resulting from some of th types of treatment the children have to receive to make their tim more pleasant, and certainly make them have less fear of the ver necessary treatments that go into prolonging their lives.

Also, as Mr. Sullivan has pointed out, we have horror stories fro all over the country in our various groups on children who ar misdiagnosed, and this has played an important part on their longevity, for example because of the lack of knowledge on the part o some pediatricians and the family physicians who are the first ones to examine the child, many times the child will be initially diagnose as neurotic instead of cancerous.

Also, there is another area that we would like you to stress. W know that there are some nutritional studies that are being done a NCI now, but there is no coordination of the data from these nutritional studies and application at the clinical level.

As parents, we have seen the very important part that nutritio plays in the treating of children with cancer who are on drug regimens.

When you are in a carcinogenic situation and are on some of thes massive drug regimens, you have to be very careful of the type o food you are ingesting. You do not want to complicate the problem the drug is giving you but to give your system the best type o defense.

These are the sorts of things that we, as parents, see in the treatment of our children.

We are parents, we do not want to practice medicine.

However, at this point, many times the parent has to practice medicine because there is no data available and disseminated to the treatment centers that there are certain forms of diet that are going to be most beneficial in a certain type of drug treatment.

We thank you, Mr. Chairman, for your past efforts on our behalf, and we certainly are interested in answering any questions that you might have that our expertise might touch on.

Senator Kennedy. That was very powerful testimony and very helpful to the committee.

I understand, you support the legislation and the amendments incorporated in the bill.

Mr. Sullivan. Yes, we do.

Senator Kennedy. You refer to it in the course of your statement and I think you elaborate on it, but these points are very worthwhile.

We will ask Dr. O'Conor and Dr. Rauscher, who was in charge of the data bank, for some responses to your points on nutrition. We will also explore what they are doing with regard to your points about the anesthetic for lumbar punctures, in addition to some of the other points you have raised here.

Let us see if we cannot begin to develop an open line of communication.

Mr. Sullivan. We would appreciate that.

We started 4 years ago, and it has expanded all across the country.

Mrs. Monaco. As Mr. Sullivan pointed out before, we have been concerned about the personnel problems and the job slot problems, and we stress this again, that for 2 years we have been talking about this and, suddenly, because of a public outcry and the work of this committee, the positions have been released.

Further, as Mr. Schmidt pointed out, this position release and authorization has not gotten down to the level of the NCI clinical treatment center re the level of the nursing and supportive personnel. They have many programs up there, and with the current status of drug treatment could prolong the comfortable lives of many children who have gotten to a low point and who need to have their own immune systems built up to continue their fight.

It is a shame to see the facilities that can save lives stand empty because the personnel are not available to make sure these facilities are properly utilized.

Senator Kennedy. Well, I hope you will keep the heat on. I think it is terribly important that we do.

I think the reason we have seen as much progress in this area as we have is the very deep and legitimate concern of citizens like yourselves. I hope you will keep knocking on the doors and hollering from the belfries. I am sure you will.

Let me again thank you.

Our next panel consists of Dr. Emil Frei III, director, Children's Cancer Research Foundation of Boston, Mass.; accompanied by Dr. John Durant, director, Comprehensive Cancer Center, University of Alabama, Birmingham, Ala.; and Dr. Jesse L. Steinfeld, chairman, Department of Oncology, Mayo Clinic, Rochester, Minn.

Gentlemen, we are glad to welcome you. You testified before th committee as the former Surgeon General, Dr. Steinfeld.

For the witnesses who are here we will just keep on with ou hearing and not break. We will have to recess around 2:00 to vot but we will continue on.

Dr. Frei is a distinguished researcher at a marvellous center, as al the centers are.

I appreciate your presence and look forward to your comments.

## STATEMENT OF DR. EMIL FREI III, DIRECTOR, CHILDREN'S CANCE RESEARCH FOUNDATION, BOSTON, MASS.; ACCOMPANIED B DR. JOHN DURANT, DIRECTOR, COMPREHENSIVE CANCE CENTER, UNIVERSITY OF ALABAMA, BIRMINGHAM, ALA., AN DR. JESSE L. STEINFELD, CHAIRMAN, DEPARTMENT O ONCOLOGY, MAYO CLINIC, ROCHESTER, MINN.

Dr. Frei. Thank you, Senator Kennedy.

It is my privilege and honor to have been chosen as successor t Dr. Sidney Farber, founder and previous director of the Children' Cancer Research Foundation in Boston. This organization wa started 26 years ago, and, until the past several years, has bee devoted primarily to patient care and research in cancer and leukemia in children.

In view of the increasing progress in the treatment of childhoo cancer and with the increasing number of basic and clinical researc leads with respect to cancer, Dr. Farber initiated a program approximately 5 years ago to substantially enlarge our cancer center. Thi has led to the construction of the Dana Center, a 17-story buildin which will open this year and essentially triple our resources fo clinical care and research. The Dana Center will be devoted primarily to clinical care and clinical research for adults with cancer. Thu in a sense, our center which was recently named a comprehensiv cancer center by the National Cancer Institute is both old and new

While we have autonomy with respect to programing and th utilization of resources, we are part of Harvard University and th Harvard Medical School and our appointments are made through th Harvard academic system. Through a formal Memorandum of Understanding developed by the university, the medical school, th Harvard hospitals and our cancer center, the relationship betwee the hospitals and the center has been carefully defined.

This, I believe, is a prototype organization for a strong autonomous cancer program integrated and interacting with a medica school and university that has extensive expertise and resources i the basic and clinical sciences generally. Let me illustrate how suc an organization may work to the advantage of the patient, clinician and scientist.

Immunology is an extremely promising area for clinical and basi research in cancer. Harvard Medical School has an extraordinaril comprehensive and strong program in immunology. We have recently recruited an outstanding young man to head our program a the Cancer Center in tumor immunology. In addition to his basi

d clinical work in tumor immunology, he interacts and works very
osely with clinical and basic scientists at the medical school work-
g in other aras of immunology.

This interaction has proven highly effective. Developing basic con-
pts and techniques in immunology are immediately communicated
d, where appropriate, applied to tumor immunology programs at
e center.

When, and if appropriate, such observations are applied in the
inic. Thus, we both have our cake and can eat it in the sense that
e have a strong autonomous highly focused cancer program and at
e same time, we have the help, good will, and interaction with and
ersonnel and material resources of the Harvard general hospitals
nd medical school.

Parenthetically of course, we are available to them when our
inical and research developments are appropriate to their interests
nd needs. This pattern of development applies to other clinical and
ientific disciplines relating to cancer such as chemotherapy, phar-
acology, virology, etc. This development has been very substan-
ally facilitated by the National Cancer Act.

I would like to turn from the general to the specific and illustrate
o areas of clinical research. Prior to 20 months ago osteogenic
rcoma, as indicated in this illustration, was associated with spread
the lungs, starting within a few months and by 12 to 18 months,
me 80 percent of the patients had lung metastases. Starting 20
onths ago, we employed combination treatment involving vincris-
ne, methotrexate and citrovorum factor.

I won't go into the details of this treatment except to say that of
e 14 patients treated starting 20 months ago, only one has devel-
ed lung metastases. When this is presented in terms of survival,
u will note that prior to July 1972, only 40 percent of patients
mained alive at 20 months whereas 100 percent of the patients
hose treatment was started during the past 20 months remain alive.

Thus, there is preliminary evidence that major progress has been
chieved in the treatment of an otherwise highly fatal tumor. This
rogress has been achieved in the past 2 years, as a result of the
pplication of laboratory and clinical research in cancer.

The next illustration shows results in the treatment of acute lym-
hocytic leukemia achieved during the past 18 months at the Chil-
ren's Cancer Research Foundation. Of 60 patients 96 percent en-
red complete remission and of these, 92 percent remain in complete
mission at 18 months. If one plots the survival from time of
iagnosis, 92 percent of all patients remain alive at 18 months. If one
xtrapolates this data out to 5 years, based on assumptions derived
rom previous studies and other diseases, more than 50 percent of
atients will remain in complete remission, that is, free of clinical
nd laboratory evidence of disease. Of patients who remain in com-
lete remission for 5 years, over 50 percent should remain disease
ree indefinitely. As you know, there has been steady progress in the
reatment of acute leukemia.

I want to emphasize that this progress has been so substantial that
xperience in recent years is entirely consistent with the realistic
ope that definitive control of at least some patients with this disease
as been achieved and will increasingly be achieved.

These two examples of progress that I have presented to you can be most readily accomplished when the medical, paramedical and research expertise, material resources and patients are concentrated in a cancer center. This is essential since the delivery of cancer services, clinical cancer research and basic research in cancer is becoming increasingly multidisciplinary; that is, it takes a team effort.

It is extremely important, and it has indeed been a charge of the National Cancer Act to the comprehensive cancers centers to play a leadership role in what is known as cancer control or the outreach program. Briefly defined this means that the very best of patient services in cancer ranging from prevention, detection, diagnosis, treatment, followup and rehabilitation be made available to every American. In addition, progress in clinical services and treatment such as I demonstrated should be extended to the community as rapidly as possible. Accordingly, we have recruited a top-flight leader for our cancer control program and are working in collaboration with the other major cancer programs in the Boston area in developing a cancer control or outreach program.

Ultimately, patient care services must and should be delivered in the community and the emphasis of our cancer control program is, wherever possible, to assist communities and community physicians in developing clinical cancer programs.

Such programs will have continuing relationships to the regional comprehensive cancer center in areas of postgraduate education, patient referral, emergency and elective telephone consultations and other interactions.

The enlargement of our cancer center, the increased resources for patient care, clinical and basic research and our community outreach program has been made possible through the National Cancer Act.

I would emphasize that while considerable progress has been made in cancer, and while we have come a considerable way, we have still a longer way to go. Thus, the Children's Cancer Research Foundation, in addition to increasing its resources through private support will be calling on the national cancer program for continuing and increasing support for our enlarging program.

We are by no means fully funded for maximal activity. It should be emphasized that we work very closely with the national cancer program and many of our clinicians and scientists interact with the clinical and scientific activities of the National Cancer Institute and serve in major advisory capacities.

In summary, the original basic justification for the National Cancer Act was that cancer represents a major health problem for Americans and that there were many research developments and leads both at the basic and clinical level, which indicated that expanded support for cancer activities, whether in cancer centers or elsewhere, was a good health investment.

The National Cancer Institute was initiated only 3 years ago, and while it has had growing pains, I believe these pains represent exactly what they are, signs of growth and health. It is not surprising that scientists disagree on the relative emphasis that should be given to, for example, immunology as compared to chemotherapy research. The fact is that both of the above disciplines have, and will continue to contribute to progress in the control of cancer and must be supported. It is also not surprising that clinicians and scientists disagree on the relative merits of a mission-oriented program such as a cancer center as compared to cancer-related research in the traditional university system. Both are essential since certain types of progress in the control of cancer can best be achieved in mission oriented cancer centers while others are best achieved employing more traditional approaches.

Scientists and clinicians may take extreme positions and such positions are often most vocal and newsworthy. I would hope that you would not be deterred by the controversies and flack that attend the enlarging cancer program but rather that you would recognize them as the pains that occur and are essential to rapid growth and progress.

I wish to thank the committee on behalf of our center and of cancer workers all over the world and most particularly on behalf of patients whose health will be benefited by the National Cancer Act and its continuation.

Senator KENNEDY. Dr. Durant?

Dr. DURANT. Senator Kennedy, I want to thank you for the opportunity to talk to you and to tell you today about the development and progress of the Comprehensive Cancer Center in Birmingham.

I am speaking to you today, not only as director of the center but also as the president of the Alabama Division of the American Cancer Society, representing 43,000 volunteers. The subject of cancer research and control has been particularly important to me since I became philosophically committed to the importance of cancer centers in 1962 to 1963, the year when I was a fellow supported by the National Cancer Institute Training Grant at Memorial Hospital in New York City.

The first thing which made the center in Birmingham, Ala. possible was the combination of outstanding enthusiasm and support of the people of Alabama and the existence of the National Cancer Act of 1971. However, more importantly the real impetus to the development of our center began in 1968, with a human tragedy, the death of a young person in the prime of life, namely our former Governor, Mrs. Lurleen Wallace. Concerned about the distance she had to travel to the M.D. Anderson Hospital and inspired by her personal courage, the people of our State responded to a private fund-raising effort of the Governor, Mr. Albert Brewer. Over 40,000 people contributed a total of nearly $5 million, virtually all of which has been collected. The purpose of this money was to provide matching funds for the development of a cancer center in Alabama. Alabamians were used to supporting important health care measures, having seen a major academic medical school grow up in a quarter of a century, watched the development and contributions to cancer of the Southern Research Institute, and repeatedly returning to the Senate the Honorable Lister Hill. Fortunately, for us, the National Cancer Institute had a program with funds to support a planning grant for the development of a center in Alabama. From 1970 to 1972 we received approximately $225,000 to work out the plans of our program. In addition, the Alabama regional medical program, through its local regional advisory group provided additional planning funds of $161,493 to plan a regional program in radiation therapy. These funds not only provided help in getting started, they also provided tremendous impetus for interest in cancer among both patients and physicians. This has increased our influence on the delivery of medical care tremendously.

I believe that there are two fundamental problems facing humanity in relationship to cancer. The first is the gap in our knowledge concerning certain fundamental information about the cause and biology of cancer. The second is concerned with the gap in delivering to all of the people the best of what we already know. There tends to be some kind of artificial division in the minds of many people who insist on making one or the other of these of primary importance. This should not be. Both can and should go on together as there will be no sudden breakthroughs which will suddenly abolish the problem but rather the gradual development of knowledge and techniques, and the application of these to clinical situations. Centers must and can stimulate progress in both of these areas. I believe the early results from our own efforts will confirm this.

In 1968 when I first came to Birmingham from Philadelphia, the number of new cancer patients seen at the University of Alabama Hospital and the Birmingham Veterans Administration Hospital were approximately 1,200 per year, or about 12 percent of the expected new cases for the entire State.

In 1973, only 5 years after the planning began and not quite 2 years after the award of our first center grant, approximately 2,300 patients were seen, or 23 percent of the expected new patients from the entire State.

We believe that our experience with the outcome in patients seen at our center supports the importance of the center concept. In review of all of our patients from 1958–72 our cumulative 5-year survival was 42 percent, a considerable difference from 33 percent, the widely publicized figure put out by the American Cancer Society.

In the period from 1968–72, our cumulative 5-year survival was 47 percent with a standard error of 3.5 percent, meaning that there was only a 5-percent chance that a survival rate above 40 percent was a statistical accident.

Furthermore, the epidemiologists and the statisticians in our cancer center assure me that these results are not due to special selection or distribution of cases.

In other words, the data seem to support the notion that referral to a major cancer center, such as ours and others like it can and does result in improved survival and that the creation of a center will result in an increasing number of patients having access to the diverse and complicated expertise of the facilities available at that center.

Our own efforts have been directed in two major ways. We have worked hard at developing basic, laboratory research programs directed at and answering some of the fundamental questions regarding the nature of cancer. We have been given the support to recruit and begin a program in the area of medical genetics which may ultimately answer fundamental questions about the ordinary control of cellular growth and division which is lost when cancer develops within a cell. We have supported research that has indicated some of the ways in which chemicals ordinarily not carcinogenic in themselves may act with other chemicals to increase greatly the potential to produce a cancer.

We have supported research which offers promise of understanding the development of the immune system and how alterations in this system can result in malignancy within the system itself or in the rest of the body. These are but a few of the programs whose growth and contributions have been aided by the development of the center in Birmingham. Each of them is, incidentally, improved and made more efficient by the fact that they have had to withstand peer review, the most single important factor in maintaining scientific excellence.

Not only have we supported basic, fundamental research, we have also worked very hard at developing a regional program which can respond to the direction of the original legislation which directed centers to develop programs which would involve practicing physicians of the region. In Alabama this is a necessity. We are one of the most indigent of the 50 States. We have one of the poorest physician-population ratios in the Nation. In order to address ourselves to meeting these sorts of problems it has been necessary to develop plans to utilize to the fullest scarce resources, personnel, facilities—particularly radiation therapy—and knowledge. We have developed a model telephonic consultation service which, although available to any physician with any kind of a patient problem, has seen calls about cancer become the most frequent category of request.

We have been enthusiastically received by physicians practicing radiation therapy in Birmingham, Anniston, and Huntsville, the areas in which the demonstration project is now working.

We have begun plans for a network for the treatment of patients with diseases of the blood and blood forming organs and have a specially trained nurse visiting regularly, a practicing oncologist in Mobile and Montgomery, and we are working out plans for extensive programs in the rehabilitation of patients with cancer.

We are working with the American Cancer Society in its "Let No Woman Be Overlooked" program to get a Pap smear on every woman in the State. The chief of our gynecological cancer service is active in that program which proposes to begin the collection of Pap smears on special populations of high-risk patients in eight of the highest risk counties spread throughout the State.

We have also worked at the development of facilities and personnel. We now have 58 physicians and investigators supported by 41 technical personnel in our program. This represents considerable growth since 1968. Through the generosity of the National Cancer Institute Center's program, we have been awarded $3.5 million in renovation and construction grants in the past 2 years. Almost all of this money is currently either being spent for facilities under construction or about to be let for bid.

The ability to respond so quickly to the needs of the people and the direction of programs has stimulated the Governor to designate $2 million in revenue sharing monies to construct 80 beds at such time as these become necessary and feasible.

In summary, I believe that we have made a small but significant beginning. Since planning began in 1968, we have doubled our patient load, improved somewhat our survival rates, built programs for and trust with community physicians, and begun construction of over 60,000 net square feet of facilities.

I trust that you will believe that this is sufficient evidence to continue support of legislation which will make it possible to deliver to those 40,000 people who originally donated money to the program and also to all of the people of the State of Alabama, the progress in both fundamental research and health care delivery which they were promised and are expecting. The next 3 years will not see sudden breakthroughs in Alabama, but I trust it will see the development of additional data and progress which will result in increasing cure rates and improved quality of survival for as many of the people of our region as possible.

Senator KENNEDY. Thank you.

Dr. Steinfeld?

Dr. STEINFELD. Thank you, Senator Kennedy. It is a pleasure to be here today to testify on the 1974 amendments to the Cancer Act.

I would like to divide my testimony into the following sections: I. The Problem: Clinical and Laboratory; II. Recent Accomplishments: Clinical and Laboratory; III. The Cancer Act; A. Strengths; B. Weaknesses; and IV. Recommendations.

## I. THE PROBLEM: CLINICAL AND LABORATORY

Cancer will strike over 50 million Americans now alive—one of four of us in this room. One of six will die as a result of that cancer. This means that today one of three American victims of cancer is cured of his tumor using surgery and/or radiotherapy and/or chemotherapy. Obviously there is hope.

In the above figures lies the dilemma facing both biomedical research scientists and the Congress. We do not know the final or ultimate cause or causes of cancer. We do not know that final event by which a virus, chemical, or radiation changes a normal into a neoplastic cell.

And we are not certain who, where, or when such a discovery will be made; or how it will be translated into a preventive or curative measure for human cancer.

Because this is unknown—many members of the scientific community urge you to support "basic science"—biochemists, molecular biologists, geneticists, immunologists—because we are so far from understanding the nature of the neoplastic cell. And, of course, they are correct.

We need more fundamental information in oncology as well as all of biology. We need to train and nurture the brilliant, inquisitive young student, so that we can learn more about man and his diseases. Our bright and research-oriented youngsters are one of our most precious natural resources and we must train them, and provide the kind of career promise and stability which will attract them into science. This is important.

Cancer funds should be used to support both training in and the conduct of basic biomedical investigations.

But that is not all of the story. Six hundred and fifty thousand Americans will develop cancer this year and 350,000 will die of the disease. Many could be saved even though we do not know the ultimate cause of cancer, through what we do know about prevention, early detection and adequate treatment.

Currently we are, without any question, saving patients' lives, even though, I repeat, there is much about cancer that we do not know. Moreover, it is quite possible that in the final analysis cancer will turn out, like infectious diseases, to be many diseases.

Indeed, I have estimated that there are over 200 different human cancers.

Several centuries ago, physicians might have talked about curing or finding the cause of fever or infection at a time when they did not have instruments sufficiently fine to see bacteria or viruses. Even then, however, it was possible through sanitation, good nutrition, good hygiene, and vaccines to combat successfully many of the infectious diseases.

Similarly, with cancers. We can prevent many cancers, if, for example, our citizens would stop smoking cigarettes. We can also prevent other cancers by prohibiting the release of carcinogenic agents into our home or work environments.

We can identify high-risk groups with certain cancers, do diagnostic tests at regular intervals to pick up tumors at a stage when they are curable.

And, finally, we can use our tools more intelligently and in combination in the treatment of cancer: combining surgery, radiotherapy and chemotherapy and possibly immunotherapy in order to improve results. And all of this can be done now.

Mr. Chairman, it is obvious that we must both improve our present diagnostic and therapeutic armamentarium, and we must do more research on fundamental biological processes.

I would interpret the arguments you have heard about basic science versus the national cancer program as coming from the uninformed. This is not an either-or proposition.

I have interpreted the Cancer Act the Congress passed several years ago as recognizing the need to work simultaneously on both problems; and that was a wise decision.

I believe that in the renewal of the legislation, you can help bring the scientists together by making more explicit the dual nature of the thrust the Congress has proposed, and by earmarking to a certain degree funds for both programs. I will return to this in the recommendations later.

## II. Recent Accomplishments: Clinical and Laboratory

It is the nature both of science and medicine that advances cannot be predicted, so that some of the progress in clinical oncology, as well as in basic oncology, has been made by scientists not wholly affiliated with the national cancer program. But most of the advances can be traced directly or indirectly to the support of the National Cancer Institute or the American Cancer Society.

In the past few years we have identified a group of young women at risk to development of vaginal cancer because their mothers were given the chemical, diethylstilbestrol, to prevent miscarriage during the first trimester of pregnancy.

More data has been obtained linking the body's immune system to cancer development since patients treated with immunosuppressive agents to permit renal transplantation have been found to have 35 times the expected rate of lymphomas.

Recent National Cancer Institute studies have shown that advanced non-Hodgkin's lymphoma patients can survive with control of the disease for long periods by combination chemotherapy.

In a large repetitive screening program—every 4 months—at the Mayo Clinic for heavy smokers at high risk to lung cancer, previously unsuspected lung cancer has been detected and localized during a subsequent screening, after the first tests were negative. In all but one of these patients it has been possible to remove the tumor surgically. This program, if successful, may represent a way to improve the otherwise dismal prognosis of the lung cancer patient.

Additional results are accumulating, showing higher survival in patients receiving chemotherapy after presumed curative surgery in tumor types with a very poor prognosis.

This may be the most significant clinical advance of all; in that it will stimulate well-controlled prospective combination treatment studies in the common cancers, which kill so many in the United States.

In the laboratory, great strides have been made in our understanding of animal tumor viruses, their transmission and multiplication.

In man, Herpes viruses have been implicated by immunologic techniques in carcinomas of the oropharynx and genitourinary tract. The carcinoembryonic antigen, CEA, and alpha-fetoprotein have been further studied as guides to the successful treatment of cancer and/or the extent of tumor within an individual patient.

At the cellular level, a component of the cell membrane, a glycoprotein, has been found to disappear when normal cells are transformed into cancer cells. This seems to be associated with appearance of an enzyme called a protease; and when the protease is inhibited, the cancer cells stop growing.

Of course, the number of advances in both clinical and laboratory science are enormous.

I want only to emphasize that the Cancer Act of 1971 has not slowed but, in fact, has speeded up progress at all levels.

## III. The Cancer Act

### A. STRENGTHS

1. The Cancer Act has focused the attention of the scientific and medical community, all of our citizens, the Congress and the executive branch of government on the cancer problem.

2. It has provided increased funds for clinical and laboratory research as well as for cancer control.

3. It has attempted to avoid bureaucratic interference with cancer programs by providing a direct budget link from the National Cancer Institute to the Office of Management and Budget, and by creating a cancer panel to monitor progress monthly and report delays and obstructions directly to the President.

4. It has recognized the need for a critical mass of physicians and scientists to achieve optimal clinical care and has required the establishment of a network of comprehensive cancer centers. These centers not only should provide a nationwide network for cancer diagnosis and treatment, but should become regional centers for cancer control and also should become centers of excellence in cancer research.

### B. WEAKNESSES

1. The Directors of the National Cancer Institute and the National Institutes of Health have become political appointees rather than career scientists.

2. The number of comprehensive cancer centers to be named is too few to provide the type of care the Congress visualized as being within a day's driving distance for most citizens of the United States.

3. The act does not provide a specific budget, either in relative or absolute terms, for the training of biomedical scientists.

4. The act does not provide personnel within the National Cancer Institute in any way commensurate with the added resources in dollars. Not only intramural programs but extramural programs as well require scientific, managerial, and supporting personnel to operate them effectively. As an example, two National Cancer Institute wards at the Clinical Center are not in operation today because nursing personnel slots or ceilings are not available.

5. The act does not require adequate outside peer review of both contract and grant programs. This is important when the executive branch of Government decides for other purposes to eliminate large numbers of advisory committees, as has occurred this past year.

6. The act does not provide guidance as to what programs should be funded by which mechanism: grant or contract. Such guidance could insure a specific or percentage amount of grant-funded basic research.

7. Finally, the act proposes a truly national cancer program and plan, yet the National Cancer Institute functions administratively much as before, despite the great increase in its budget and responsibilities.

Mr. Chairman, these recommendations are made within the context that research can be carried out through a number of different administrative mechanisms.

First, the National Cancer Institute was functioning effectively within the NIH prior to the enactment of the plan of 1971; second, it could function well if the original act creating a separate agency for cancer research had been passed by the Congress.

However, the following recommendations are made within the context of the act as it was finally passed. Parenthetically, I would say a word here about the budget.

I certainly agree with Dr. Stone, Dr. Rauscher, and Mr. Schmidt that the cancer program should not be mounted at the expense of other Institutes at NIH.

I was very pleased to hear Secretary Weinberger indicate that the extra $100 million for cancer research the President proposed today would not be at the expense of other Institutes, and particularly pleased to hear Mr. Schmidt defend the need for additional resources within the other Institutes.

I should point out, if we add up the numbers, the President is proposing $100 million in addition to his original fiscal 1974 budget proposal of $500 million, whereas the Congress passed $540 million for cancer research in fiscal 1974. Moreover, there are some additional funds released from impoundment (approximately $50 million) so the latest increase should be viewed in this light.

I submit those numbers so the record will be clear.

Now, as to the actual recommendations regarding the act.

## IV. Recommendations

1. The Director of the National Cancer Institute and of the National Institutes of Health should be career appointees. Politicization of National Cancer Institute and NIH should cease.

Senator Kennedy. You would be opposed to a Presidential appointment?

Dr. Steinfeld. I think if the Director of NIH and of National Cancer Institute were within the career system and were to make a decision which did not appeal to his political superiors, those scientists would still have the protection of either the Civil Service Commission or the Commission Corps system, and I think in many instances this would be extremely valuable. The people who do not have this career protection are not quite as free to do what their scientific judgment directs. So I think career appointments would be an advantage.

2. The number of cancer centers to be designated in the next 3 years should be increased to 30. A definite number is desirable and can be reviewed again in 3 years.

3. A portion of the National Cancer Institute budget should be reserved for training the research scientists and clinicians of tomorrow.

Senator Kennedy. You are satisfied there is scientific expertise and manpower to provide the kind of support that Mr. Schmidt mentioned earlier to 30 centers of some excellence?

Dr. Steinfeld. I think they could be developed and I believe within the next 3 years, this should be our goal.

I think 15 does not blanket the country the way the Congress indicated, and I do think naming centers is an excellent idea because it leads to the form of cooperation that both Dr. Frei and Dr. Durant described.

I think naming them is a good idea, and having the number 30 would probably reach the goal Congress had in mind for the Nation.

Senator KENNEDY. We do not set it precisely, but we have indicated that this figure is approximately 30 to 35.

Obviously, I think we would be guided by how those resources could best be utilized.

I think the thrust of our amendment on this is to achieve what you have outlined here, and I am glad you support it.

Dr. STEINFELD. I certainly support that amendment, and think it is an excellent one.

We need not only research scientists but clinicians expert in the diagnosis and treatment of cancer as well as in cancer control. Funds should be provided to institutions rather than individuals, so as to stabilize institutional funding in a period of rapidly changing academic and governmental responsibilities.

I think a very real problem has developed over the past few years in which training funds go to the individual rather than to the institution.

4. The act should provide a specific number of personnel—scientific, medical, managerial, and supportive—to carry out the purposes of the act. If the cancer program is a national priority research and medical program, the Office of Management and Budget should provide personnel as well as fiscal resources to carry out the Congress' and the President's decisions.

5. Both grants and contracts should be reviewed by outside peer groups. The mechanism for choosing peer review groups should be changed to provide a mechanism for input from the Congress, the American Association for Cancer Research, the American Society for Clinical Oncology, and the National Academy of Sciences.

6. The contract mechanism should be restricted to use for the purchase of products or services. It should be used to purchase research only after such resrach programs are recommended by senior outside scientific review bodies.

7. The Congress should take some responsibility for implementation, or at least continuing oversight of the cancer program; and for review of the choice of Cancer Panel, Board, and scientific review body membership within the National Cancer Institute.

This last may be the most controversial, but also the most significant of the recommendations. It is common knowledge among the scientific communities that the Directors of the various Institutes at the National Institutes of Health seldom have their choices for National Advisory Council members approved.

I believe recommendations for the Cancer Board should come from a group composed of the Director and Deputy Director of the National Cancer Insttute and a representative from each of the American Association for Cancer Research, the American Society of Clinical Oncology, and the National Academy of Sciences.

The nominations should be nonpolitical, and should be submitted for informational purposes to the chairman and minority leader of both the Senate and House committees responsible for oversight of the cancer program at the same time that they are submitted to the President of the United States.

The same elected Members of Congress should receive the Cancer Panel's monthly report and should meet at least quarterly with the Cancer Panel and the Director of the National Cancer Institute to review programs and problems.

While in the past many of the scientific groups have been chosen entirely intramurally by NIH staff, the magnitude and the scope of the national cancer program require that the members of all senior scientific committees be selected in such a way as to insure scientific objectivity and immunity from political surveillance.

Having greater participation of the scientific community in the choice of advisory groups and having bipartisan congressional overview of the program, should make the program more truly an initiative of both the legislative and executive branches of Government.

In conclusion, the Cancer Act of 1971, endorsed overwhelmingly by both the legislative and executive branches of Government, was not only a reflection of our Nation's desire to conquer cancer but an expression of our dissatisfaction with the current priority for cancer research and dissatisfaction with the current administrative and management mechanisms available to do the job.

Work, both scientific and administrative, by Dr. Rauscher and his senior staff at the National Cancer Institute has started the program successfully on the route charted by the Congress.

My purpose today is to suggest mechanisms, exclusive of dollars, which can help the National Cancer Institute, by providing for greater involvement of the Congress and the biomedical community, in achieving our goal of conquering cancer.

Senator KENNEDY. Very good, very helpful suggestions and recommendations.

We would like to stay in touch with you on a number of these proposals.

I gather that you gentlemen agree without qualification about the provision of our legislation that permits the expansion in the number of cancer centers, and feel that is a desirable feature and one that ought to be supported.

Do I understand the thrust of your testimony to include that general support?

Dr. FREI. Yes.

Senator KENNEDY. This statement will be useful both to me and to the other members of the subcommittee in the course of our deliberations.

Dr. FREI. I think the answer is emphatically yes, with the emphasis on the fact that the 15 or 18 Cancer Centers, comprehensive Cancer Centers, that now have been designated are in varying stages of development.

Some are very mature and some relatively new. I think the additional Cancer Centers, I guess it is the proposal to be added as they are over the next 3 years could take advantage of the experience not only of the old Cancer Institutes, as Dr. Clark pointed out, but also of some of the problems and opportunities of the relatively recent ones.

Senator KENNEDY. Because you have Federal funds, have you felt the cold hand of Federal takeover in any of the centers you have been associated with? Has this caused you undue concern?

Dr. STEINFELD. I certainly have not. We are the newest center, but it would seem to me in working with the National Cancer Institute staff that they are looking for help, looking for advice, and we certainly have had considerable help from National Cancer Institute staff, and nothing that would be inimical to the development of the Cancer Center.

Dr. FREI. As Mr. Schmidt emphasized, none of the comprehensive centers are totally dependent financially on the Federal Government.

All of them have a varying base of private or State support, which assures some degree of independence.

I think the comments that Dr. Steinfeld made with respect to increasing scientific input, and decreasing political input into the selection of scientific advisors for the national cancer center program, and key administrators of the national cancer center program is also important in that context.

Dr. DURANT. I would like to reiterate the testimony of the other witnesses.

I think the number of Centers needs to increase, otherwise we are likely to have two classes of citizens, those with ready access to the availability of the Centers, and those who do not.

I believe the importance of review in reviewing the programs of the Centers is essential in order to keep them scientifically excellent.

I do not consider that political interference, but scientific guidance.

We have not felt the cold hand of the Feds on our programs.

I feel that we have been tremendously helped by the National Cancer Act, and by the community of scientists around the nation who have supported this legislation.

Senator KENNEDY. I want to thank you for your testimony.

One of the goals of the legislation is to obtain firsthand information from those who have been out in the field. I think I share with all of those who support the changes in the legislation, a very strong belief that this flexibility will be used by the Institute to support excellence and availability of information to the greatest number of American citizens.

I think we are completely aligned in that understanding, and I think the clarifications that Mr. Schmidt made about ongoing commitments and limitations in this area are important and should be established in the record as well.

I want to thank you gentlemen very much. We may be submitting some additional questions to you in the course of the legislative process that lies ahead.

Thank you again.

At this time I would like to welcome Dr. John Cooper, president of the Association of American Medical Colleges, Washington, D.C.

We are delighted to have you here.

## STATEMENT OF DR. JOHN COOPER, PRESIDENT, ASSOCIATION OF AMERICAN MEDICAL COLLEGES, WASHINGTON, D.C.

Dr. COOPER. Thank you very much, Senator Kennedy.

Senator KENNEDY. I apologize for our time problem. We have two votes back to back by 2:30, and the full committee goes into executive session at 3 o'clock, so we will have a bit more time to hear from the final witnesses.

Dr. Cooper. May I say that we have a fairly extensive statement, which I think describes fairly completely our views on the legislation you have introduced, and some other recommendations which we are making.

As you know, we did express our views and recommendations on the establishment of a separate Cancer Institute when the National Cancer Act was considered in 1971, and our statements on that issue are already on record.

After the extensive debate in Congress the National Cancer Act was passed, and the Director of the National Cancer Institute was placed in a special position within the National Institutes of Health. We expressed our concern at that time about the possible adverse effects of the singling out of one institute for special status and authority, and what effect that would have on the other research institutes.

Some of these adverse effects have come to pass. For example, during the past few years the budget and staffing requests by the administration for the other institutes have decreased dramatically, while the budget requests for the Cancer Institute have increased sharply. The full meaning of the situation is not clear, but the association nevertheless is still deeply concerned about the implications because of its concern with the welfare of all the NIH research institutes.

In order for the cancer program to be effective there must be effective research programs in all of the other disciplines. If these activities are not adequately staffed and funded, the effectiveness of the cancer program—as well as our conquests of other diseases—is going to be impaired.

In contrast to what Secretary Weinberger said this morning, the administration has not been in the position of merely preventing what he called the "Japanese rate of increase" of funding for the Institutes. In fact, the administration has requested less money in fiscal 1972 through fiscal 1974 than it did in the budget of 1971.

The association wants to point out that the administration has attempted to prevent the growth of these Institutes, at least as evidenced in the budget requests it has sent to the Congress. Fortunately, the Congress appropriated more funds for these years. The administration impounded these funds, and continued to limit spending to the rate originally requested in its budget. During this past year, the association and other organizations were successful in prosecuting a lawsuit for the release of that money—at least we think it has been released.

I do want to point out that there has been a cutback in all of the other Institutes, and there has been a substantial reduction in the staffing of those Institutes. Mr. Schmidt and others have raised concern with regard to the ability of the staff of the Institutes to carry out the intent of the legislation, and to protect the interests of the U.S. Government. There have been substantial cutbacks in the number of positions available, and there is a real question about whether there is enough manpower in these Institutes to really effectively manage the programs. This is one area that the association hopes the subcommittee will look into, along with the particular staffing needs of the National Cancer Institute.

The association has made some recommendations in the testimony submitted for the record with regard to changes that might be made in the present national cancer program which would strengthen and improve it. I would like to summarize these points.

First, the association agrees with the other witnesses and recommends that all research contracts have scientific peer review, not only at the time of the awards, but also when requests for contract proposals go out, so that there will be scientific input as to their nature and scope.

The association thinks the National Cancer Advisory Board should have this responsibility. The Board, of course, could assign the more routine kinds of contract authorizations, such as the procurement of special drugs, and other routine contracts to the Director of the National Cancer Institute. The Board should, however, have the responsibility and authority for assuring peer review of the proposals that go out, and assessing the responses to the RFP's.

Second, the association believes that provisions of the National Cancer Act should mandate utilization of the present NIH research training programs in the struggle against cancer. Where appropriate, language should be added to mandate the use and continuation of training stipends, fellowships, institutional support, and career development awards.

Third, the association suggests that the ceiling on the number of centers should be removed from the bill. This issue has been discussed adequately during today's hearings, so I will not go into further detail.

Fourth, the association recommends that the act's construction authority be amended to specifically include authority for basic research labs and hazard control. There has been a great deal of confusion as to whether there is authority to construct these kinds of facilities.

The association would like to make three additional recommendations of provisions that we hope would be included in this bill. One recommendation is that the statutory authority for the Secretary of HEW to enter into contracts, be included and extended in the National Cancer Act. This authority, which expires on June 30, is currently found in section 301(h) of the Public Health Service Act.

Second, the association recommends that the provisions of sections 601 of Public Law 91–296 be added to the National Cancer Act. This provision, which expires on June 30, has been very useful to organizations which have tried to prevent impoundment of funds by the administration. We would hope that language similar to section 601 would be continued, and that it would be attached to this particular bill, in which the administration has considerable interest.

Finally, the association also recommends a statutory term for the Director of the NIH. He or she would be a Presidential appointee, subject to Senate confirmation. The association believes that a 7-year term is suitable for the directorship of NIH. It would help to remove this position from the political arena and would help regain the recognition that this office is probably the top scientific job in the United States. The association strongly recommends that this provision be included.

I think, sir, that this summarizes the recommendations that we have with regard to the act, and if there are any questions now, or that you want to submit to me, I would be happy to try to answer.

Senator KENNEDY. I think that is a very helpful and useful statement.

Your support of the increased numbers of research centers is quite welcome. We reiterate our responsibility to continue adequate funding of the various Institutes.

Dr. COOPER. And the staffing is a very serious problem in other institutes. Mr. Chairman, they have had great losses in the number of staff, and with the current level of the program activity there is a real question whether they can really carry out their responsibilities.

Senator KENNEDY. Your suggestion is some form of oversight hearing or function by the committee to deal with these problems.

A number of the specific observations you have made have been very helpful. We are going to work out some of the details and the legislative language.

We probably expect as much from Mr. Goldman.

Dr. COOPER. We have known Mr. Goldman for some time. We would urge that section 601 be continued in this bill.

Senator KENNEDY. That is very helpful, too.

Doctor COOPER. Section 601 is important, not only to the cancer program, but to all programs. The administration is interested in this bill, but it may not be interested in section 601.

Senator KENNEDY. That is music to our ears.

Thank you very much. Your full statement will appear in the record at this point.

[The prepared statement of Dr. Cooper follows:]

ASSOCIATION OF AMERICAN MEDICAL COLLEGES
SUITE 200, ONE DUPONT CIRCLE, N.W., WASHINGTON, D.C. 20036

# STATEMENT BY THE ASSOCIATION OF AMERICAN MEDICAL COLLEGES ON LEGISLATION TO CONTINUE THE NATIONAL ATTACK AGAINST CANCER*

Mr. Chairman and Members of the Subcommittee:

The Association of American Medical Colleges welcomes this opportunity to present its views on the extension of the National Cancer Act of 1971.

The Association is the national organization of institutions engaged in the formal education of M.D.s either at the undergraduate or graduate levels. It is comprised of all of the 114 medical schools in operation in the United States, 400 of the major teaching hospitals, and 51 academic societies which encompass the teaching and research faculties of academic health centers. The Association was formed in 1876 and has been an important force in the evolution of medical education over the intervening years.

The constituent institutions and organizations of the Association are concerned not only with undergraduate medical education but also with the training of research scientists and the medical specialists and clinicians essential to bringing the advances of present day medicine to the health care of the American people. Within the laboratories and clinical facilities of these institutions is conducted a substantial portion of the total medical and health related research effort of the nation. Thus, the Association and its membership have a deep and direct involvement in the issues before the subcommittee today.

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* A statement presented by John A. D. Cooper, M.D., President of the Association of American Medical Colleges, before the Health Subcommitttee of the Senate Committee on Labor and Public Welfare, January 30, 1974.

The Association presented its views and recommendations regarding the establishment of a separate, independent cancer institute when the National Cancer Act was under consideration in 1971, and its previous statements on this issue are on record. After extensive debate and consideration of the issues involved in launching an independently targeted, national attack to conquer cancer, the Congress in its wisdom provided specific statutory authorities for the National Cancer Institute and its Director which were not shared by the other components of the National Institutes of Health.

The Association expressed its concern about the possible adverse impact that the singling out of one institute for special status and authority would have upon the other institutes and divisions at the National Institutes of Health. During the past few years, budget requests and staff positions for the National Cancer Institute have increased dramatically, while the total budget request and staffing for the remaining research components of the NIH have been reduced. The full meaning of this situation is not clear, but the Association is nonetheless deeply concerned about its implications because of the Association's concern for the welfare of all of the NIH research programs. In order for the cancer program to be effective, it must have input from the other bioscience disciplines. If these activities are not adequately staffed and funded, the effectiveness of the cancer program must necessarily be impaired.

The Association and its membership are in agreement that extensive biomedical research efforts are essential if medical science is to discover the causes and to develop cures and treatment for this complex of killer diseases. The Association believes that several provisions could be added to the current cancer authority which would further strengthen the attack gainst cancer, and that additional provisions could be included in other ections of the Public Health Service Act which would help assure that ollateral research efforts in the other institutes are not impaired because f continual shifts in policy and management or because of reductions in unding and personnel.

In order to improve the national cancer program, the Association ecommends that:

1. the scientific review provisions of the National Cancer Act be mended to add external peer review of research contracts to the present uthority for peer review for research grants and programs, and to allow he National Cancer Advisory Board to delegate to the Director of the ational Cancer Institute final authority over routine procurement contracts;

2. the research training provisions of the National Cancer Act be mended to mandate the utilization of present research training programs n the struggle against cancer;

3. authorizations for cancer research and control programs be extended or three years;

4. the present 15-center ceiling on the number of cancer research and emonstration centers be removed; and

5. the NCI Director's construction authority be expanded to include uthority for basic research laboratories and biohazard control.

In addition, the Association recommends the following because of its oncern with the overall integrity of the federal biomedical research effort:

1. that the general authority of the Secretary to enter into research ongracts, which is to expire June 30, be extended indefinitely;

2. that general language requiring the timely obligation and expenditure of funds appropriated for cancer research and for related purposes be added to the subcommittee's legislation; and

3. that present language providing for Presidential appointment of the NIH Director be modified to require Senate confirmation of the nomination and to specify a fixed term of office for the NIH director.

Each of these recommendations deserves some more detailed comment.

## Peer Review of Contracts

The use of non-federal scientists to review grant applications for biomedical research projects to be funded by the federal government has assured a broad, non-federal voice in the formation and implementation of national policy. The peer review system which has been developed and utilized for NIH grants has assured a rigorous assessment of the scientific merits of research projects for which NIH grant support is being sought. This process of scientific appraisal carried out by disinterested and expert scientists has resulted in the use of public funds only for the support of biomedical research which has met the highest standards of excellence

The Association believes that, because of the substantial amount of public funds that are becoming available for the award of cancer research contracts, it is imperative that these contracts also be subject to scientific scrutiny -- at all stages of the contract process, including Requests for Proposals (RFPs) and at the final award. The collective judgments of assembled outside experts will help to assure that contract-related decisions are based on scientific merit. The process of peer review has been recognized as an effective mechanism in assuring maximum scientific returns for public investments in research grants. A similar maximum return should also be sought for similar investments in research contracts.

In another contract-related issue, the Association recommends that the esent requirement of National Cancer Advisory Board review of all contracts modified to exclude such routine matters as normal procurement contracts, f laboratory supplies, for example. Such authority could be delegated by e Board to the NCI Director. The intent of the recommendation is to free e Board from the burden of routine administrative review of such recurring ntract actions and thus to allow the Board additional time for consideration more important, large research and treatment awards. Language similar in tent was provided in 1971 for swift consideration of routine research grant plications, and the Association regards that as a useful precedent for imilar modification now of the contract review mechanism.

search Training

The research training programs of the National Institutes of Health ave provided specially trained research manpower in critically short pecialized areas of research needs, such as virology, which are becoming f increasing importance in the continuing quest for the causes and cures f cancer. These programs have assured the constant flow into research fields f individuals with advanced training in the biomedical sciences who are most ikely to produce the new ideas and pursue the new and unknown paths into he cancer complex.

The continuing need for these young researchers and the programs which rain them has been recognized in legislation currently pending in the ongress, HR 7724, which would assure that research training is to be ontinued. The amendment the Association is recommending is designed to nsure that the National Cancer Institute will be able to utilize the research training authority which the pending research training legislation provides. The amendment mandates the availability of research training authority for the NCI rather than providing -- as the present law does -- only discretionary availability of such authority.

The Association recommends that Section 407(b)(7) be amended to read as follows:

> "(7) Support appropriate manpower programs of training in fundamental sciences and clinical disciplines to provide an expanded and continuing manpower base from which to select investigators, physicians, and allied health professions personnel, for participation in clinical and basic research and treatment programs relating to cancer, including the use of predoctoral and postdoctoral training grants (including both stipends and institutional support), fellowships, and career awards."

### Authorizations

The Association recommends further substantial authorization levels for a broadly based balanced national cancer effort.

Perhaps more important than the detailed comments and suggestions which the Association has already advanced is its concern about the imbalance in the overall NIH programs which has resulted since enactment of the National Cancer Act. This runs the risk of losses in research in important areas of medicine. For example, constriction of work in molecular biology may hamper fundamental work necessary for the understanding of the cancerous process. Therefore, the authorization levels for the national cancer program must be considered in close relationship to the projected support levels for the other NIH research institutes and divisions.

The Association is concerned about what happens when one takes the total NIH research appropriations over the last five years, and extrapolates the next three years. If one assumes that the NCI authorizations are appropriated in full, then the expenditures for the NCI would increase about 12 percent per year, but all other activities would be either unchanged or, in some instances, be forced to decline.

cer Centers

The Association's recommendation to remove the present 15-center ceiling the number of national cancer research and demonstration centers is designed avoid possible delays in translating laboratory findings into the care treatment of cancer patients. If there is to be maximum public access cancer care and to be maximum professional access to cancer research, development of a national network of cancer centers must not be hampered rigid legislative barriers. In order to best serve the needs of the ulation, the establishment of additional comprehensive cancer centers may essential in speeding the nation towards its dual objectives of making prehensive cancer treatment available to all Americans and intensifying earch efforts aimed at understanding and conquering this dread disease.

struction Authority

The Association's fifth recommendation would clarify the scope of the 's construction authority.

Section 410(2) of the Act provides authority for the Director of the ional Cancer Institute to construct cancer centers, laboratories, and earch facilities. This language does not specify that the construction hority also includes authority for basic research laboratories and hazard control facilities. The specific inclusion of these items in ction 410 would remove any doubt over the scope of the construction hority. The Association therefore recommends that Section 410 be nded accordingly.

The Association's more general recommendations also require some additional comment and discussion.

## General Contract Research Authority

The general contract authority for biomedical research and investigation is contained in Section 301(h) of the Public Health Service Act. This authorization will expire on June 30, the same day as expiration of current cancer authorizations. The Association believes that the present legislation would be a most appropriate vehicle for the extension of this important contract authority, which provides authority for all the research institutes and divisions of the NIH, not solely for the Cancer Institute.

The Association recommends the following language:

> "Section 301(h) of the Public Health Service Act is amended to read as follows:
>
> (h) Enter into contracts, including contracts for research in accordance with and subject to the provisions of law applicable to contracts entered into by the military departments under title 10, United States Code, sections 2353 and 2354, except that determination, approval, and certification required thereby shall be by the Secretary of Health, Education, and Welfare; and ".

## Availability of Funds

In order to insure that funds appropriated by Congress for cancer and other related health activities will be made available for expenditure and obligation, the Association recommends that the following language be included in the pending legislation:

> "Notwithstanding any other provision of law, funds appropriated for any fiscal year to carry out any program for which appropriations are authorized by the Public Health Service Act (Public Law 410, Seventy-eighth Congress, as amended) or the Mental Retardation Facilities and Community Mental Health Centers Construction Act of 1963 (Public Law 88-164, as amended) shall be made available for obligation and expenditure no later than the end of such fiscal year."

Similar language is presently contained in Section 601 of PL 91-296, nd is to expire on June 30, the same day that the current cancer authorities xpire. This language has been used frequently in recent months to secure e availability of funds appropriated by Congress but not released for ligation and expenditure, including funds for cancer research. This gislation -- because it deals with cancer research -- is a most appropriate hicle for the continuation of this Congressional directive that appropriated alth funds, and the priorities which they reflect, are not to be tampered th. The importance of this language to the federal investment in health nnot be overemphasized. The Association therefore urges the subcommittee take this opportunity to extend this crucial statutory protection.

tatutory Term for NIH Director

The Association believes that the establishment of a statutory term of ffice for the Director of the National Institutes of Health is essential to e continuity of leadership in biomedical research. Federal support of his research is a nonpartisan activity, and its leadership should be equally onpartisan. It is imperative that the director of the federal biomedical esearch effort be a highly qualified individual, with a background and raining in biomedical research and administration, who is selected without egard to political affiliation. The administration of the research effort ill be best served by the nonpolitical transition from one director to he next, with careful Congressional review of the scientific qualifications f proposed directors.

In order to meet these goals, the Association strongly urges the ubcommittee to provide a statutory term of seven years for the Director f the NIH and to make appointment subject to Senate confirmation.

The Association therefore recommends that Section 454 of the Public Health Service Act be amended to read as follows:

> "(a) The Director of the National Institutes of Health shall be appointed by the President with the advice and consent of the Senate, to serve for a term of seven years; he or she shall be eligible for reappointment. Before any person is appointed Director, the President shall afford the National Academy of Sciences an opportunity to make recommendations to the President with respect to such appointment.
>
> (b) The Director of the National Cancer Institute shall be appointed by the President. Except as provided in section 407(b)(9), the Director of the National Cancer Institute shall report directly to the Director of the National Institutes of Health."

Additional Association Comment

The Association has repeatedly stressed that the basic causes and nature of the cancerous process are unknown. The nature of cancer is deeply embedded in the most elemental life processes and is an obscure and complex part of the life cycle. Major further progress in the conquest of cancer is, in the final analysis, dependent upon greater understanding of the intricate working of the basic life cell and its responses to both internal and external forces.

It is important to realize that the new leads which seem to offer promise for advances in cancer have emerged in scientific fields which at the same time were far removed from the mainstream of scientific effort in cancer. These new efforts are derived from, and are dependent upon, scientifi achievements in the fields of virology, immunology, genetics, and cell biology. No one can predict with certainty the fields from which will come the findings that will provide further insights into the nature of cancer. All bioscientists, however, will agree that real progress in understanding cancer can only come through greater understanding of the fundamental life processes of which it is a part.

The national attack upon cancer cannot be fought exclusively with rograms sponsored by the National Cancer Institute. Cancer research is lso dependent, in part, upon advances in the various biosciences which re sponsored by the other institutes at the NIH -- particularly the general asic research programs of the National Institute of General Medical Sciences.

The Administration's failure to perceive the importance of the other IH disciplines in the national attack against cancer is evident not only in he lowered budgets of these institutes, but also in the distribution of taff positions within the NIH. Over the past several years, the NIH s a whole has suffered an outright loss of approximately 600 permanent full-me staff positions. In addition, over 350 more positions have been transferred rom the other institutes of the NIH to the NCI and the National Heart and ung Institute. The net result has been a loss of approximately 950 staff ositions within the other institutes of the NIH -- a loss which has seriously ompromised the ability of the NIH staff to administer the programs under ts direction.

The impact of the Administration's decisions on the morale and effective-ess of NIH administrators is clear. The national biomedical research program stablished by the Congress has been stymied by administrative fiat. The epeated attempts to terminate research training programs, abolish peer review, nd reorganize staffing patterns indicate all too clearly that biomedical esearch and the nation's health do not hold a high priority within this dministration. Such an attitude cannot be allowed to stand unchallenged.

Senator **Kennedy**. Our final witness is the American Cancer Society, represented by Dr. A. Hamblin Letton.

He is chairman of the Society's Legislative Committee and its national chairman.

We welcome you to the committee this morning, and apologize for the late hour.

## STATEMENT OF A. HAMBLIN LETTON, M.D., CHAIRMAN, LEGISLATIVE COMMITTEE, AND PAST PRESIDENT, AMERICAN CANCER SOCIETY

Dr. **Letton**. Thank you, Mr. Chairman.

I am Dr. A. Hamblin Letton of Atlanta, Ga. I am in the private practice of surgery.

I am the former chief-of-staff of the Georgia Baptist Hospital, the largest private hospital in Georgia, and am president of the Atlanta Medical Center.

I am the chairman of the Patient Care and Research Committee for Cancer of the American College of Surgeons, and am a member of the Professional Education Committee of the International Union Against Cancer.

I am a volunteer of the American Cancer Society and have held the chairmanship of almost every important committee of the American Cancer Society, as well as being national president in 1972.

I am here today to present to you the views of the American Cancer Society on the renewal of the Cancer Act legislation.

The American Cancer Society has been very pleased with the progress of the National Cancer Institute under the leadership of Dr. Frank Rauscher and the President's Cancer Panel, operating within Public Law 92–218, the National Cancer Act of 1971.

We, without hesitation, endorse and encourage the passing of the proposed amendments to Public Law 92–218, which we believe will make the national cancer program more effective. We strongly support the increase in funding authorizations for the next 2 years, both in the budget of the National Cancer Institute and the cancer control program.

We strongly support the special authorities and initiatives the National Cancer Act gives to the National Cancer Institute, including direct budget submission to the President with reasonable opportunity for comment, but without change by the Secretary of HEW, and the Director of the National Institutes of Health. This has been one of the healthiest changes in the history of the National Cancer Institute. We would strongly oppose any action that would return the control of the National Cancer Institute to the National Institutes of Health.

We support the increase in the number of experts or consultants as defined in section 401(1). We urge the deletion of the word "fifteen" in section 408(A).

We support the increase in funding authorization as has been suggested by the National Cancer Advisory Board; that is, for the cancer control program $50 million for fiscal 1975, $65 million for fiscal 1976, and $85 million for fiscal year 1977.

And for the National Cancer Institute budget, $750 million for 1975, $830 million for 1976, and $985 million for 1977.

This, of course, is far short of the $1 billion which was contemplated for fiscal 1976 by the Panel of Consultants to the U.S. Senate for the Conquest of Cancer. It is also a far cry from NASA's budget of $3 billion in a year when NASA is supposedly curtailing its activities. NASA has spent $54 billion so far.

The 1971 law is not specific concerning the amount of overhead in the limitation of $35,000 in grants in section 410(b) (1) and (2). We would urge that the law be changed to read so that the $35,000 includes only direct costs.

The reason here revolves around the uncertainty of the costs, which vary widely from one institution to another, and the size of the indirect costs, which often leave a sum too small for practical use.

Indirect costs are not controlled by the National Cancer Institute. Rather, they are negotiated by the institution and higher levels of Government and then applied to any grants from the Government to the individual institution. So far as the National Cancer Institute is concerned, there is no opportunity for either waste or economizing with regard to the negotiated indirect cost rate applicable to any given grant.

For instance, institutions of higher education operated last year at indirect costs of 64 percent, 52 percent, and 59 percent, among other rates applicable in that geographic area. A noneducational institution in the same area received grants on which a 53-percent indirect cost rate applied.

Scientists reviewing $35,000-maximum projects face uncertainty, in these circumstances, of the proposal's feasibility.

The authority for construction is not specific in the 1971 law. This should be more specific, applying to new building as well as that which is specified in the 1971 law: ". . . To acquire, construct, improve, repair, operate, and maintain cancer centers, laboratories, research, and other necessary facilities and equipment, and related accommodations . . ." in section 410(2). This has been interpreted to bar new construction of basic cancer research facilities.

However, new construction is explicitly needed. One important use for this building is the control of biohazards. The virus work is one of the most important new frontiers. It requires particular care for isolation, atmospheric control, positive waste disposal, cleansing, and personnel traffic.

Occupationally acquired cancer among researchers is a distinct possibility. The consequences of laboratory exposure to experimental carcinogens may not be demonstrated for many years. Prevention now is imperative to reduce hazards to a minimum.

The 1971 cancer law authorized 15 new clinical centers. As of today we have not met that goal, though we expect that the National Cancer Institute will be able to designate the full number by June 30 of this year when the present law expires.

The Institute has designated three world-recognized comprehensive cancer centers as fitting the law's intent, but only nine "new" centers have been designated as such since the law went into effect.

I am submitting for the record a list of these centers. We need more.

The outreach of designated centers simply cannot be extensive enough to serve the whole country. Such major cities as San Francisco, Atlanta, Kansas City, Chicago, New Orleans, Memphis, Pittsburgh, and many others are without comprehensive centers.

This means unavoidable delays in putting into the mainstream of medical advances those new discoveries, new treatments, that emanate from the conquest of cancer program. And it means that patients needing highly specialized treatment available only at such centers must often travel hundreds of miles from their families for that care. We have enclosed a map designating the locations of the approved centers.

The 15-center limit in the law should be removed.

Personally, I want to add that all the American Cancer Society volunteers are grateful to you and to this committee for your consistent and dedicated support of the Cancer Act and its program. We are confident that the program has advanced our fight against cancer in the last few years.

The effects of such a program are not always easy to see unless one is engaged in patient care, but we who are in the practice of medicine are confident that the ideas and improvements brought forth are going to prove very valuable as we view the cure rate of cancer in the years to come. We must push this fight with vigor through renewal of the cancer law.

Historically, the American Cancer Society has been extremely interested in the work of the National Cancer Institute. The National Cancer Institute was established in 1937 by the Congress, largely as a result of interest and efforts of the American Cancer Society.

Through the years the Institute and the Society have cooperated. However, the independence of the National Cancer Institute, as authorized by the National Cancer Act of 1971, has brought this into a never-before-realized cooperative partnership with the American Cancer Society.

This legislation has produced a unique form of Federal-private cooperation. In the area of cancer control, the American Cancer Society and the National Cancer Institute are actively sharing funding, planning, and administration of several cancer control projects as part of the national cancer program.

This represents a first in the Government-private sector relationship, the benefactors of which are the American people, both in the service rendered, and in the savings to them because of the volunteers of the American Cancer Society.

Were the Government required to pay for all of these man-hours of labor, the cost would be astronomical. The American Cancer Society with its over 2.5 million volunteers, including the professional expertise of over 50,000 doctors, has provided this involvement without cost to these projects.

I would like to describe one example of this cooperation, and I refer to the joint American Cancer Society/National Cancer Institute breast cancer detection demonstration program.

The object of these project units is to demonstrate to the practitioners and to the public the effectiveness of early detection of breast cancer, to better define the high-risk groups and to develop better screening methods—see attached list of leaders and locations of project units.

Breast cancer mortality rates have remained constant at about 25 per 100,000 for the last 40 years. The incidence, however, has increased from 65 to 72 per 100,000. Therefore, we are curing more women.

We lost 8.5 times as many women during the years of the Vietnam war than we lost servicemen in Vietnam. In a 10-year period the number of women in the United States having breast cancer would outnumber the population of Boston, Mass., man, woman, and child.

The National Cancer Institute and the American Cancer Society have established 27 projects throughout the United States in the breast cancer detection program. The response of the public and the profession has been overwhelming.

Each project will examine 5,000 women each year. In my own project we are now booked up into next fall with women clamoring for this examination.

This is a wonderful example of the public's realization that somebody cares about them and is doing something for them—it is wonderful public relations for the National Cancer Institute, for the Congress, and for the President.

We do not yet have the figures from all of the projects, but in my own, in Atlanta, in the first 1,300 women we screened, we found 8 cancers, only 1 of which was large enough to be felt clinically and only 1 of which had any evidence of spread.

The results of this cooperative effort will result in a highly significant reduction in the death rate from cancer of the breast, which is the number one killer of women in the United States.

Mr. Chairman, we have made great progress in the first 3 years under the National Cancer Act. The Congress is dedicated, the President is dedicated, the American Cancer Society remains dedicated as a committed partner. This is an unbeatable team.

We, therefore, urge the renewal of this legislation for the sake of the survival of the untold thousands of men, women, and children, the future victims of cancer. May this act preserve them, that they may enjoy this great country of ours in the years to come.

Mr. Chairman, this is a great country, yet, there are many things we could do better, but it is the greatest country on this earth.

Last year I met with health educators behind the Iron Curtain in Krakow, Poland. In discussing cancer education among medical students, Dr. Glazer, who is professor of surgery at Leipzig University in East Germany, said that they had difficulty in teaching cancer education, because the government demanded that 25 percent of the time of the curriculum in medical school be dedicated to the teaching of Leninism and Marxism.

We are fortunate in the United States that we have been able to keep politics and medicine separate. The cooperative efforts of the Government and the private sector, as is demonstrated by the National Cancer Institute/American Cancer Society partnership can only survive in such a society free of politics, free to answer the needs of our people: the need to give and the need to receive.

Thank you.

Senator KENNEDY. Thank you very much. That is a splendid statement. We are interested in your comments about the budget and personnel in the independent centers, and these are very helpful comments for us to have.

You are in support of the program?

Dr. LETTON. It is in accord with the bill as I see you have suggested.

Senator KENNEDY. Is the figure of 25 per 100,000 or more?

Dr. LETTON. Twenty-five per 100,000 is the number of deaths of cancer of the breast among women for the last 40 years.

However, the incidence has risen, and these are the figures, from 55 per 100,000 to 72 per 100,000 is the incidence of cancer of the breast. We are curing more women, but our mortality rate has remained at this 25 per 100,000.

Senator KENNEDY. Is that because people are living longer?

Dr. LETTON. This is one of the reasons that we have people in the older age group coming in now.

There seems to be an increase in the number of cancers of the breast.

Senator KENNEDY. Why is that?

Dr. LETTON. We do not know at the present moment. I wish we did, Mr. Chairman.

Senator KENNEDY. We want to thank you very much.

At this point I order printed the statements of those who could not attend and other pertinent material submitted for the record.

## AMERICAN CANCER SOCIETY/NATIONAL CANCER INSTITUTE

### Breast Cancer Demonstration Projects

### East

| | Project Director | Date Awarde |
|---|---|---|
| Albert Einstein Medical Cntr.<br>Temple U. Hospital<br>Philadelphia, Pa. | Harold J. Isard, M.D.<br>Marc S. Lapayowker, M.D., Associate | 2 Jan 74 |
| College of Medicine and Dentistry of New Jersey<br>Newark, New Jersey | Benjamin Rush, M.D. | 28 June 73 |
| Guttman Institute<br>New York, New York | Philip Strax, M.D. | 18 April 73 |
| Rhode Island Hospital<br>Providence, Rhode Island | Herbert P. Constantine, M.D. | t.b.r.# |
| U. of Pittsburgh School of Med. | Bernard Fisher, M.D. | u.n.* |
| Wilmington Med. Cntr. | Leslie W. Whitney, M.D. | 1 Jan 74 |

### South

| | | |
|---|---|---|
| Duke University Med. Cntr.<br>Durham, N.C. | Richard G. Lester, M.D. | u.n. |
| Emory U.--Georgia Baptist Hosp.<br>Atlanta, Georgia | R. Waldo Powell, M.D.<br>A. Hamblin Letton, M.D. | 9 May 73 |
| Georgetown U. Med. School<br>Washington, D.C. | Margaret Abernathy, M.D. | u.n. |
| St. Vincent's Med. Cntr.<br>Jacksonville, Florida | Marvin A. McClow, M.D. | 6 June 73 |
| U. of Louisville School of Med. | Condict Moore, M.D. | 17 April 73 |
| Vanderbilt U. School of Med.<br>Nashville, Tennessee | John R. Amberg, M.D. | t.b.r. |

### Midwest

| | | |
|---|---|---|
| Ellis Fischel State Cancer Hosp.<br>Columbia, Missouri | William L. Donegan, M.D. | t.b.r. |
| Iowa Lutheran Hospital<br>Des Moines, Iowa | Donald C. Young, M.D. | u.n. |
| Medical College of Wisconsin<br>Milwaukee, Wisconsin | James E. Youker, M.D. | 18 June 73 |
| U. of Cincinnati Med. Cntr. | Myron Moskowitz, M.D. | 28 June 73 |
| U. of Kansas Med. Cntr.<br>Kansas City, Kansas | Loren J. Humphrey, M.D. | 19 June 73 |
| U. of Michigan Med. Cntr.<br>Ann Arbor, Michigan | Walter M. Whitehouse, M.D. | u.n. |

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*u.n.--under negotiation

#t.b.r.--to be reviewed Feb. 1974 by ACS, then by NCI; to receive award in FY 1974 if NCI money is available.

## West

| | | |
|---|---|---|
| Good Samaritan Hospital & Med. Cntr. Portland, Oregon | Morton J. Goodman, M. D. | t. b. r. |
| Mountain States Tumor Institute Boise, Idaho | Alfred M. Popma, M. D. | 25 June 7 |
| Pacific Health Rsch. Institute Honolulu, Hawaii | Fred I. Gilbert, Jr., M. D. | 19 Dec 73 |
| St. Joseph's Hospital Houston, Texas | Duncan L. Moore, M. D. | t. b. r. |
| Samuel Merritt Hospital Oakland, California | Robert Schweitzer, M. D. | u. n. |
| U. of Arizona Med. Cntr. Tuscon, Arizona | Arthur J. Present, M. D. | t. b. r. |
| U. of Oklahoma Health Sciences Cntr. Oklahoma City, Oklahoma | JoAnn Haberman, M. D. | 18 June 73 |
| U. of Southern California Los Angeles, California | Lewis W. Guiss, M. D. | t. b. r. |
| Virginia Mason Rsch. Cntr. Seattle, Washington | Thomas Carlile, M. D. | 14 June 73 |
| Statistical Center University City Science Center Philadelphia, Pa. | W. C. Ellenbogen | 29 June 73 |

### Awarded to 16 Jan 74

| | |
|---|---|
| ACS Funds | $ 999, 304 |
| NCI Funds | 1, 998, 608 |
| (Statistical Cntr. NCI Funds | 489, 068) |
| Total | $3, 486, 980 |

### Under Negotiation & Review

| | |
|---|---|
| ACS Funds | $1, 300, 000 |
| NCI Funds | 2, 600, 000 |
| Total | $3, 900, 000 |

## National Cancer Institute

### Established Comprehensive Centers

(In Thousands)

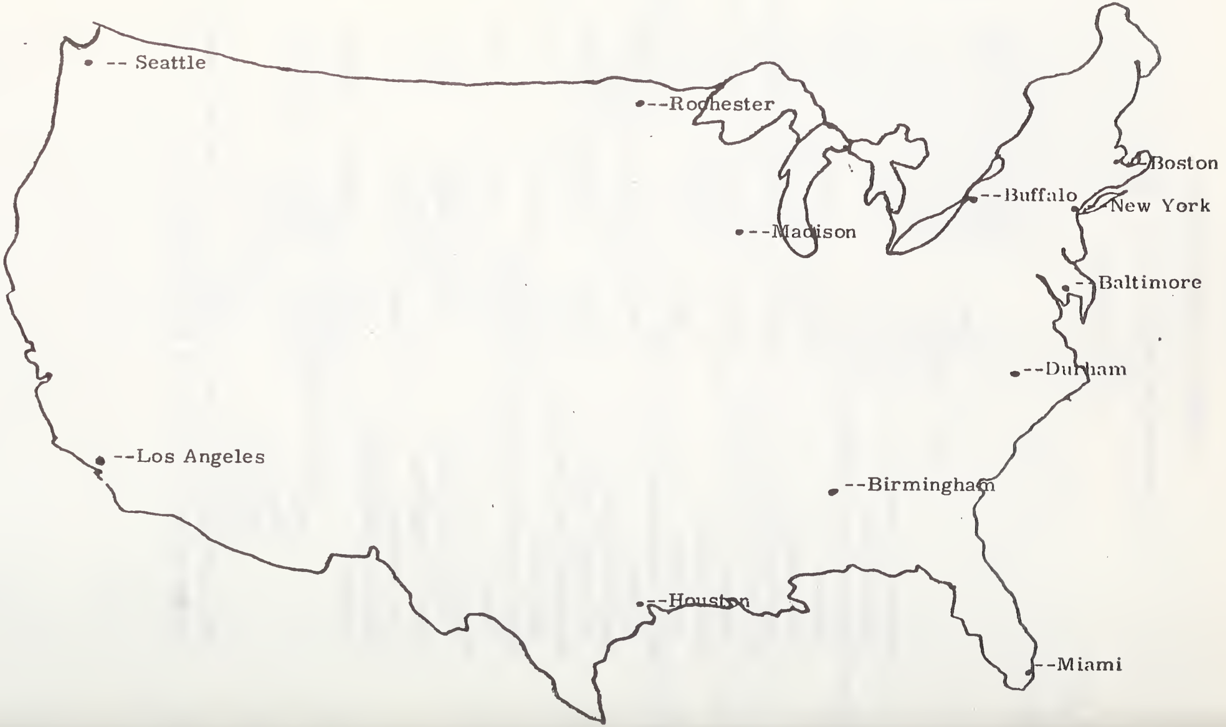
| | | All Other Grants and Contracts | | |
|---|---|---|---|---|
| | Core Grants | Research Grants Only | | Fiscal 1974 Total * |
| Alabama University Birmingham | $ 907 | ($ 1,295) | $ 813 | $ 1,720 |
| Children's Cancer Rsch. Boston | 1,188 | ( 3,600) | 2,977 | 4,165 |
| Duke University Durham, N.C. | 952 | ( 401) | 2,524 | 3,476 |
| Hutchinson Cancer Center Seattle | 700 | ( 2,011) | 5,010 | 5,710 |
| Johns Hopkins Baltimore | 969 | ( 1,751) | 3,817 | 4,786 |
| M. D. Anderson Houston | 905 | ( 2,708) | 8,298 | 9,203 |
| Mayo Foundation Rochester, Minn. | 862 | ( 1,214) | 1,273 | 2,135 |
| Memorial Sloan-Kettering New York | 6,369 | ( 13,580) | 14,189 | 20,558 |
| Miami University Miami | 375 | ( 938) | 2,333 | 2,708 |
| Roswell Park Buffalo | 371 | ( 2,515) | 7,051 | 7,422 |
| Southern California U. Los Angeles | 654 | ( 2,012) | 17,711 | 18,375 |
| Wisconsin University Madison | 706 | ( 4,044) | 13,767 | 14,473 |
| Total | $14,968 | $36,069 | $79,763 | $94,731 |

* NCI plans for 1974, based on a $589 mil. budget which would include money released from FY 73 impoundment.

Geographic Distribution
of

National Cancer Institute

Comprehensive Cancer Centers


-- Seattle
--Rochester
--Madison
--Buffalo
Boston
New York
Baltimore
--Durham
--Los Angeles
--Birmingham
--Houston
--Miami

# CURRICULUM VITAE -- A. HAMBLIN LETTON, M.D.

January 1974

President of the National American Cancer Society, Inc., 1971-1972.

Surgeon in Private Practice.

Fellow of the American College of Surgeons.

Chairman, Patient Care and Research Committee, American College of Surgeons.

Chief of Staff, Georgia Baptist Hospital (Georgia's Largest Private Hospital).

Fellow of the Southern Surgical Association.

Diplomate, American Board of Surgery.

Member of the American Goiter Association.

Member of the Society of Nuclear Medicine.

Member of the Ewing Society.

Secretary-Director of Southeastern Surgical Congress.

Member of the Board of Directors, Georgia Division, American Cancer Society, Inc.

Active Attending Surgeon, Georgia Baptist Hospital.

Surgical Consultant, Scottish Rite Hospital.

Member of the Georgia Science and Technology Commission.

President, Atlanta Medical Center.

Consultant for the Georgia Division of Vocational Rehabilitation.

Member of Board of Judges, Mutual of Omaha.

Listed in Who's Who of America and Who's Who in the World.

Member of the Board of Directors, University Yacht Club.

Second Ponce de Leon Baptist Church, Deacon (inactive).

AMERICAN MEDICAL ASSOCIATION
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ERNEST B. HOWARD, M.D.
Executive Vice President

February 5, 1974

The Honorable Edward M. Kennedy
Chairman, Subcommittee on Health
Committee on Labor and Public Welfare
United States Senate
Washington, D. C. 20510

Dear Senator Kennedy:

On behalf of the American Medical Association, I would like to submit for your consideration our comments on S. 2893, the "National Cancer Act Amendments of 1974."

The bill before your Committee would amend and extend, for three years, the programs of the National Cancer Institute, and would provide increased funding to carry forth those activities now under way.

As you will recall, the AMA enthusiastically endorsed an increased national effort to seek cures for cancer and methods of preventing these diseases when Association representatives appeared before the Congress in 1971 to offer our support of the National Cancer Act during its original consideration. At that time, we recognized the need for the advocated increased funding of the cancer program. We continue to believe that the programs of the National Cancer Institute deserve a high priority and would recommend their continuation for another three years, and we are in basic support of this legislation. We would like to offer our comments on some of its specific provisions.

The Association supports the amendment to Section 402(b) of the Public Health Service Act which would authorize the Director of the National Cancer Institute to approve grants for cancer research or training without reviewing recommendations by the National Cancer Advisory Board if the direct cost of research and training did not exceed $35,000. We believe that this modification of ~~existing~~ existing law will relieve the National Cancer Advisory Board of an unnecessary burden of review of many small grant applications. The National Cancer Advisory Board could then concentrate its attention on major cancer research or training projects.

Under the present authority of Section 407(a)(7) of the Public Health Service Act, the Director of the National Cancer Institute is required, among other duties, to support appropriate manpower programs of training in fundamental sciences and clinical disciplines including, where appropriate, the use of training stipends, fellowships, and career awards. The legislation before you would delete the term, "where appropriate," thus making the use of training stipends, fellowships, and career awards a basic part of the program. We believe that this is an appropriate amendment to the present Act and recommend its support.

Section 408(a) of the present Public Health Service Act authorizes the Director of the National Cancer Institute to provide for the establishment of 15 new centers for clinical research, training, and demonstration of advanced diagnostic and treatment methods relating to cancer. The legislation before you would delete reference to the limitation of 15, thus leaving open the number of centers which could be established under the Act. At the present time, there are 18 cancer centers, 15 of which were established under the bill and 3 existing centers which have received grants to strengthen their activities.

We share with the Secretary of HEW a belief that the present number of cancer research centers are adequate to meet the needs and programs envisioned by the present Act. If, after a careful examination of the presently operating 18 centers, and their ability to carry out their essential mission of demonstrating the best methods of cancer treatment, there is found a demonstrable need for more centers, then such additional centers should be specifically provided for, by number in legislation. We believe that the present 15 center limitation should be continued until such time as the need for additional centers is clearly demonstrated. We would urge that the limitation in present law be retained.

We believe that the broad spectrum of medical research merits increased support if we are to deal adequately with the major illnesses that cause disability and death. We must question whether the large amount of money being appropriated for cancer research can be effectively used or whether some of that money could be better used in other facets of medical research. We would urge that funding for cancer research be viewed in light of the total medical research activity currently under way in this country.

Increased funding for cancer must not compromise other research programs to the detriment of the nation's total health effort.

We have one further concern, which is not addressed by provisions of the legislation before you, which we believe is worthy of consideration by your Committee. The AMA believes that the attack upon cancer can be most effectively conducted by restructuring the administration of the National Cancer Institute to put it under the control of the Director of the National Institutes of Health.

At the present time, the National Cancer Institute is a relatively autonomous agency with its own budget. However, cancer is a multi-faceted problem that involves, among other elements, environmental contamination, genetics, cell metabolism, immunity, and perhaps infection by viral agents. Therefore, it is clear that the effort to cure cancer, if it is to be successful, will have to be a coordinated effort with the full involvement of all the National Institutes. This is a fact which is widely recognized and accepted throughout the scientific community. In addition, it would seem prudent to keep NIH intact rather than to continue to have it fragmented into independent agencies which compete for support and recognition rather than collaborate for scientific progress. We believe that the present administrative arrangement impairs the effectiveness and productivity of the entire NIH organization and fragments and diminishes the overall scientific effort of the National Institutes of Health.

In conclusion, we would like to reiterate our support of a 3-year extension of the National Cancer Institute but would urge a continuation of the limit, in present law, of 15 centers for clinical research, and training, and demonstration of advanced diagnostic and treatment methods relating to cancer. We would also urge that the administration of the National Cancer Institute be placed under the control of the Director of the National Institutes of Health.

Thank you for this opportunity of presenting these views. I respectfully request that this letter be made a part of the record of your hearings of S. 2893.

Sincerely,

EB Howard

Ernest B. Howard, M.D.

MICHAEL B. SHIMKIN, M.D.
PRESIDENT
UNIVERSITY OF CALIFORNIA
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1144 SILVERADO ST.
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HUGH J. CREECH, PH.D.
SECRETARY-TREASURER
THE INSTITUTE FOR CANCER RESEARCH
7701 BURHOLME AVENUE, FOX CHASE
PHILADELPHIA, PENNSYLVANIA 19111

April 24, 1973

The Honorable Gaylord Nelson
The United States Senate
Senate Office Building
Washington, D.C. 20510

Dear Sir:

The attached policy statement was unanimously endorsed by the members of the American Association for Cancer Research at its annual meeting on April 12 in Atlantic City.

The statement expresses concerns and suggestions in regard to biomedical research in the United States, of which cancer research is an integral part.

We hope you may consider the statement in the legislative and budgetary processes relevant to the cancer problem and related biomedical research. We would welcome the opportunity of discussing the statement in more detail with you.

Respectfully yours,

Michael B. Shimkin, M.D.
President

MBS/gd

MICHAEL B. SHIMKIN, M.D.
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1907

HUGH J. CREECH, PH.D.
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## POLICY STATEMENT

(April 12, 1973)

The American Association for Cancer Research includes in its membership a high proportion of the total research force of the United States that is involved in work leading to the solution of the cancer problem.

The Association gratefully acknowledges the national confidence in cancer research expressed in the Cancer Act of 1971. It accepts the responsibilities implied in this confidence.

The Association wishes to emphasize that problem-oriented research directed against cancer will prosper to the degree that it can draw on the nutrient soil of basic biological research. Research investment in cancer alone, without adequate investment in broad biologic research, will be less productive.

Truly original discoveries in science are often unpredictable and cannot be conveniently programmed. A sound research strategy must carefully balance centrally directed research with studies originating with the individual scientist.

The basis of scientific discovery is the prepared mind confronted by new or unanticipated findings. Such minds are most likely to be found among young scientists. Moreover, significant shortages have been clearly identified in several critical man-power areas. A cancer research program devoid of funds that can be applied to training is unsound, not only for the best development of new talent, but for technical capacities to translate new discoveries into improved care and treatment of the cancer patient.

The American Association for Cancer Research therefore recommends the following steps to the responsible Federal fiscal decision-makers and administrators of the National Cancer Program :

1) Prompt completion of review and prompt implementation of the National Cancer Plan.
2) Prompt release of authorized funds for cancer research for the present and future years.
3) Continued assignment of an adequate portion of the total available funds to training in critical cancer research areas.
4) Utilization of the peer-review system for the allocation of National Cancer Institute funds to assure high quality of both programmed and individual cancer research.
5) Reallocation of available funds to increase significantly the support of individual research projects, including competing initial applications.
6) Augmentation of the number of scientific staff positions at the National Cancer Institute commensurate with its expanded responsibilities.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH
BETHESDA, MARYLAND 20014
Registry of Experimental Cancers
National Cancer Institute
Bldg. 37(ERF), Room 202

August 31, 1973

Frank J. Rauscher, Jr., Ph.D.
Director, National Cancer Program
National Cancer Institute
Bethesda, Maryland 20014

Dear Dr. Rauscher:

The enclosed final report of your ad hoc Committee on Testing for Environmental Chemical Carcinogens is submitted for your consideration. It reflects the unanimous views of the members with the exception of an additional suggestion made by Dr. Saffiotti which is indicated on page 5 as a minority opinion.

The ad hoc Committee was established by you on December 7, 1972 and charged:

a. To identify and review overlapping interests and activities of various Federal departments and agencies with respect to testing of chemicals for carcinogenicity.

b. To review in particular detail the responsibilities and plans of the Pine Bluff National Center for Toxicological Research in relation to NCI activities and plans in this field.

c. To make specific recommendations as to the role the NCI should play with respect to testing of chemicals for carcinogenicity in order that it might best promote the interests of the National Cancer Program in achieving its objective of prevention of human cancer.

The members are:

Abraham Cantarow, M.D.
Paul N. Harris, M.D.
Paul Nettesheim, M.D.
Umberto Saffiotti, M.D.
Harold L. Stewart, M.D., Chairman
Albert Tannenbaum, M.D.
Arthur C. Upton, M.D.
Gerald N. Wogan, Ph.D.

The staff consists of:

Morris F. Cranmer, Ph.D.
Herman F. Kraybill, Ph.D.
Howard L. Richardson, M.D.

Two meetings, each lasting two days, were held on March 8-9 and on May 31-June 1, 1973 in Building 37, Room 1B-04. Copies of the minutes, certified by the Chairman, have already been sent to you. Copies of the minutes, approved by the Committee, are enclosed.

On behalf of the members of the Committee, its staff and Chairman, I wish to thank you for your support of our work. It is the hope of all of us that our analysis will be informative and helpful to you, and that the implementation of our recommendations will promote one of your major objectives, the prevention of human cancer.

Sincerely,

Harold L. Stewart

Harold L. Stewart, M.D.
Chairman
ad hoc Committee on testing for
Environmental Chemical Carcinogens

Enclosures

# Report
# of the
# Director's _ad hoc_ Committee
# on Testing for Environmental Chemical Carcinogens

National Cancer Institute
National Institutes of Health
U.S. Department of Health, Education, and Welfare

August 1973

## ANALYSIS AND RECOMMENDATIONS

This committee was established by the Director, NCI/NCP,

a. to identify and review overlapping interests and activities of various Federal departments and agencies with respect to testing of chemicals for carcinogenicity;

b. to review in particular detail the responsibilities and plans of the Pine Bluff Center for Toxicological Research in relation to NCI activities and plans in this field;

c. to make specific recommendations as to the role the NCI should play with respect to testing of chemicals for carcinogenicity in order that it might best promote the interests of the National Cancer Program in achieving its objective of prevention of human cancer.

Information bearing on these matters was obtained from the FDA, EPA, NCTR, USDA, NOSHA, NIOSH, NIEHS, DOD and AEC (Appendix), and discussions were held with representatives of most of these organizations in the course of the meetings of the committee.

Review of the available information led to the following conclusions:

(a) Although various governmental units are engaged in testing chemicals for carcinogenicity incident to their regulatory responsibilities or the scientific interests of their staffs, there is no legal requirement for systematic testing for carcinogenicity of chemicals present in or being introduced into the environment. The rather extensive, but comparatively limited current activities of the NCI, are the closest approximation to a program of this nature.

(b) The proposed program of the NCTR in the area of carcinogenesis devoted specifically to large-scale, low-level, dose-effect studies in the mouse, will not contribute materially to progress toward its stated objective, viz., improved capability for assessing the carcinogenic hazard for man on the basis of data obtained in laboratory animals.

The *ad hoc* Committee on Testing for Environmental Chemical Carcinogens endorses the following opinions expressed on the subject of carcinogenicity testing by other reviewing bodies:

(1) *Report of Task Force on Research Planning in Environmental Health Science, March 1970*: "Those concerned with safeguarding man's health must assure that the benefits of new technologies and new products

are attained with minimal risk to man's health and well-being. To accomplish this goal requires new approaches. Rather than depending on hope, luck and hindsight (as has often been the case up to now), more careful surveillance of the health of the population and more systematized testing of the safety of individual chemicals now in use, or proposed for the future, must be employed."

(2) Report of National Cancer Plan (OBJECTIVE 1) Panel of Experts: "Because of the potential importance and significance of environmental factors in the production of human cancer, it is essential for the NCI to establish ..... a resource that would provide a mechanism for interaction with other agencies that have responsibility for regulatory action....."

"The functions of this resource would be to interpret to the appropriate regulatory agency the significance of relevant and valid carcinogenicity testing programs developed either within the NCI or through grants and contracts let through it. Further, it would receive from such agencies questions concerning the potential carcinogenic significance of new materials found in, or about to be introduced into, the environment. It would be expected to keep abreast of all new technological developments and all new carcinogenic leads, interrelating these in a meaningful and significant fashion."

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In forming judgments as to the possible carcinogenic hazard posed by a particular environmental chemical, consideration must be given to certain important aspects of the actions of these agents. These include, among others: the long latent period; the wide variation in individual susceptibility and degree of exposure; the possibilities of exposure transplacentally (fetus) and via the mother's milk (newborn); the potential of most chemical carcinogens for producing cancers of various organs under different circumstances; the additive, synergistic and antagonistic actions of many carcinogens; the virtual irreversibility of effects of submanifestational doses; the importance, to the ultimate development of cancer, of the totality of lifetime exposure to all carcinogenic agents, chemicals, radiation and viruses.

At the present state of knowledge in the area of chemical carcinogenesis, the most practical direct approach to prevention of cancer in man lies in preventing or minimizing exposure to known carcinogenic chemicals, and to radiation. To this end, there is urgent need to identify chemical carcinogens present in, or being introduced into, our environment.

The National Cancer Act of 1971 contains the following mandates:

"407 (b). In carrying out the National Cancer Program, the Director of the National Cancer Institute shall:

"(1) With the advice of the National Cancer Advisory Board, plan and develop an expanded, intensified, and coordinated cancer research progran encompassing the programs of the National Cancer Institute, related programs of the other research institutes, and other Federal and non-Federal programs."

"(4) Collect, analyze, and disseminate all data useful in the prevention, diagnosis, and treatment of cancer....."

"410. The Director of the National Cancer Institute is ..... authorized:"

"(4) to utilize, with their consent, the services, equipment, personnel, information, and facilities of other Federal, State and local agencies, with or without reimbursement therefor;"

"(8) to take necessary action to insure that all channels for dissemination and exchange of scientific knowledge and information are maintained between the National Cancer Institute and other scientific, medical, and Biomedical disciplines and organizations, nationally and internationally."

In our opinion, these mandates imply a moral, if indeed not a legal, obligation on the part of the NCI to assume the responsibility for developing a program of systematic testing of environmental chemicals for carcinogenicity, since this is not being done by other agencies. However, the resources presently available to the NCI are wholly inadequate for this purpose.

## RECOMMENDATIONS

1. Consideration should be given to establishment of a Federal Council on Environmental Carcinogenic Hazards, analogous to the Federal Radiation Council, which formulated Radiation Protection Standards. This Council would be authorized to insure that standards are reasonably consistent with respect to criteria for testing, evaluation of test results, selection of chemical substances for testing and test procedures employed. These must reflect the best judgments of authorities in the field of chemical carcinogenesis and carcinogenicity testing, in order to insure, insofar as is possible, the validity of the experimental data and of the interpretations placed upon them.

2. In accordance with its responsibilities under the National Cancer Act of 1971, the National Cancer Institute should develop a comprehensive national program for identification of carcinogenic chemical hazards in the environment, with a view to their elimination or control. This will require close cooperation with other government agencies, non-governmental institutions and also industry, and development of a mechanism for continual and prompt interchange of relevant information.

3. The cost of the program should be borne jointly by the various agencies and organizations involved.

4. The resources required for this program should be provided without delay.

5. A unit within the National Cancer Institute should be charged specifically with the responsibility for identification of carcinogenic chemical substances in the environment. This unit should devise necessary mechanisms for:

    (a) selection of chemical substances to be tested;
    (b) design and monitoring of test procedures;
    (c) evaluation of data obtained;
    (d) formulation of recommendations to appropriate agencies based on test results.

Minority opinion.--(Dr. Saffiotti has suggested inserting the phrase "by the National Cancer Institute" following the word "establishment" in line 1, Recommendation No. 1, on page 4.)

Recommendation No. 1, as modified by Dr. Saffiotti, reads as follows:

1. Consideration should be given to establishment by the National Cancer Institute of a Federal Council on Environmental Carcinogenic Hazards, analogous to the Federal Radiation Council, which formulated Radiation Protection Standards. This Council would be authorized to insure that standards are reasonably consistent with respect to criteria for testing, evaluation of test results, selection of chemical substances for testing and test procedures employed. These must reflect the best judgments of authorities in the field of chemical carcinogenesis and carcinogenicity testing, in order to insure, insofar as is possible, the validity of the experimental data and of the interpretations placed upon them.

[From the Washington Post, Nov. 21, 1973]

## CANCER WAR'S SEPARATE STATUS A MISTAKE, DR. EDWARDS SAYS

(By Stuart Auerbach)

The government's chief health official, Dr. Charles C. Edwards, said yesterday that Congress and the President made an administrative "mistake" by giving the war on cancer semi-independent status in the federal bureaucracy.

Edwards, the Assistant Secretary of Health, Education, and Welfare for health, said that the budget for the National Cancer Institute has got to be part of the total health budget."

Two years ago, the cancer war was given semi-independent status with a direct link to the White House to make sure it gets all the money it needs. President Nixon, in signing the bill, said the cancer institute would not have to compete with agencies of government for funds.

"In spite of the law," Edwards told a luncheon of health writers and lobbyists, "I think we've worked out a very workable arrangement that can go on indefinitely."

He said that Dr. Frank J. Rauscher, President Nixon's choice to head the cancer institute, hasn't "interpreted the law in its strictest sense," which would only permit Edwards and HEW Secretary Caspar W. Weinberger to give advice on budgetary matters.

Instead, Edwards continued, "he considered himself to be part of the whole health team."

Edwards acknowledged that Rauscher had only "limited" means to declare his independence of the HEW hierarchy—the simplest of which is taking his case over Weinberger's and Edwards' heads to the people and Congress.

Edwards said the cancer budget has not suffered from the present arrangement. In 1970, the cancer budget was $180 million; this year the President requested $500 million. But Rauscher said in a memo that he really needs the $640 million that Congress authorized to do the job he is supposed to do. Edwards said the cancer institute requested $740 million in next year's budget.

Edwards said that if cancer gets so much money, other health research programs will be "destroyed."

Edwards' views were disputed in a telephone interview By Benno C. Schmidt, head of the three-man panel appointed by Mr. Nixon to oversee the war on cancer. He said the cancer program has flourished as a result of the new status and money it was given.

Schmidt said he has continually told the White House that cancer should not get added funds at the expense of other research programs, many of which supply vital leads for understanding and treating cancer.

"I think it would be a step backward to diminish the authority and responsibility of the director of the National Cancer Institute for the purpose of enhancing the power of the various levels above the director," Schmidt said.

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[From the Washington Post, Jan. 24, 1974]

## ON THE QUESTION OF AUTONOMY FOR NIH

The question of autonomy for NIH, as your Jan. 19 editorial rightly suggests, is indeed more important than the manner in which essential biomedical research is supported. And while it may or may not be simple to grant autonomy to NIH, to do that would be to eccept the view that biomedical research is not, and need not be, an integral part of our nation's efforts to solve health problems.

At a time when the annual appropriation for NIH was counted in the tens or hundreds of millions of dollars and the total federal involvement in the health care system was comparatively small, it might have been possible to treat NIH and indeed all of biomedical research as an independent part of federal health enterprise. But that era ended when the federal government became a dominant figure in the health care systems of this country. Today the annual NIH budget is more than $2 billion, federal funds pay for 25 percent of all the health care provided in the United States, and almost half of the cost of medical and other health training is borne by U.S. taxpayers.

To assume that the vital contribution of research can somehow be made more certain by insulating NIH from the serious fiscal and managerial problems that must concern us all is to yearn for a simpler, more halcyon time that is likely never to return.

Clearly we do have to restore confidence in NIH, confidence that was diminished in the past through inadequate leadership and a misguided sense of the place of research in the nation's efforts to solve its health problems. The real need is to establish effective methods for setting research priorities among the institutes and program of the NIH in order that the total biomedical research effort remain in balance. If, in fact, the NIH leadership had been more perceptive and responsive we might not have witnessed the removal of the cancer research effort from the administrative control of NIH, a move that threatens the further dissolution of biomedical research efforts.

Institutions—even the finest biomedical research institution in the world—must change. Fortunately, the need for constructive change is appreciated and welcomed by many scientists at NIH and elsewhere who do not share the sentiments of Dr. Sherman and who are determined that NIH will contribute effectively and creatively to solution of the health problems facing this country and the world.

Charles C. Edwards, M.D.,
*Assistant Secretary for Health,*
*Department of Health, Education and Welfare.*

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[From Science magazine, Dec. 14, 1973]

## Cancer: Select Committee Calls Virus Program a Closed Shop

(By Barbara J. Culliton)

The last few weeks have not been all that one might hope for the nation's premier biomedical research enterprise—the war to conquer cancer. First, assistant secretary for health Charles C. Edwards declared the whole operation an "administrative mistake." Then, a special committee of the National Cancer Advisory Board turned in a review of the multimillion dollar Virus Cancer Program (VCP) that was not exactly complimentary.

Edward's remark won him as many friends as it did adversaries. Right from the start, many, many scientists opposed the administrative scheme that set the National Cancer Institute (NCI), which is running the war, apart from the rest of the National Institutes of Health. But the National Cancer Act of 1971 was passed just the same, and the question of whether that ever should have happened became submerged as controversies arose over details about how the cancer crusade should be staged. So, a lot of people, including some members of the cancer board itself, were happy to see Edwards resurrect what they consider still to be the basic issue.

The catch is that, were Edwards to have his way by withdrawing the NCI's special status within NIH and cutting it down to size, it does not necessarily follow that future decisions about the level and style of support of cancer research would revert to the scientific community. Nor does it logically follow that less money for cancer would mean more for anyone else. What does follow is that scientific decision-making would become even more centralized within the Administration than it is now (*Science*, 2 November).

The strongest exception to Edwards's charge that the cancer program is an administrative mistake has come from investment banker Benno C. Schmidt, who is President Nixon's principal adviser on the cancer crusade. "Despite expressions to the contrary by the assistant secretary for health, it is my opinion that the National Cancer Act of 1971 is a sound piece of legislation that has worked extremely well," he told a crowd of physicians attending the National Conference on Virology and Immunology in Human Cancer, held recently in New York. The mistakes that have been made, in his opinion, should be blamed on the Administration, not the cancer legislation. Schmidt thinks it was a mistake for the Administration to cut research training grants and to reduce funds for other areas of research at a time when progress in cancer depends upon progress in other areas as well. "At the time we were urging on Congress and the Administration a greater effort in cancer, we were explicit in the position that the increased cancer effort should not be at the expense of other biomedical research. I must confess that I, for one, did not believe that would happen." Now, Schmidt admits that he was wrong.

In light of these fundamental questions about the way biomedical research in this country is going, a controversy over the NCI's Virus Cancer Program [formerly the Special Virus Cancer Program (SVCP)] seems trivial. Nevertheless, it is central to questions that are being raised about the ways in which big league, targeted efforts are being run. The answer, in this case, anyway, seems to be not very well.

### VIRUS PROGRAM CRITICIZED

For one reason or another, the Virus Cancer Program has provoked controversy ever since it began in 1964 as an organized, coordinated effort to determine whether viruses cause human cancer, and, if so, to do something about it. The VCP is operated with research contracts, rather than grants, and, according to its defenders, supports a large scientific corps for the money—1,000 researchers and 1,000 technical and secretarial personnel. Within the VCP, several groups have contracts for $300,000 or more. Some top $1 million. Today, the VCP gets 12 percent of the total budget for the war on cancer and is one of the largest contract programs within NIH.

It is not very surprising that there are a lot of people whose feelings about the VCP are anything but generous. And, although unofficial, those feelings have been well chronicled in an article by Nicholas Wade (*Science*, 24 December 1971). Last March, the cancer advisory board decided that it was time to take an official look at the virus program, and it agreed that a committee would be appointed to do so.

Appointing the committee turned out to be rather tricky when initial efforts to find cancer virus scientists without ties to the VCP, or known feelings about it, were unrewarding. In the end, the committee consisted primarily of men who are not working directly in cancer virus research.[1] Norton Zinder of Rockefeller University is chairman.

The so-called Zinder report, which probably will not be released for several months, was presented to the cancer board in closed session at its recent meeting. Members of the committee, the board, and the VCP were present.

The report begins by stating that the committee fully accepts the probability that viruses cause at least some human cancers and that it believes studies in virology can lead to a basic understanding of a tumor cell. It concludes that the VCP is, therefore, a perfectly sensible kind of program to have and states quite explicitly that it should be continued. Just the same, the report, in the committee's own judgment, has a decidedly "negative tone."

"Should this single funding instrument [the VCP] *as it currently operates* have so large a fraction of the sources that support cancer virology at its disposal? It is the view of this ad hoc committee that the answer to this question is "No." Among other quarrels it has with the VCP, the Zinder committee challenges the assumption that the time is ,or was, ripe for the program's goals to be attained. "It is now 10 years and a quarter of a billion dollars later, and the same two objectives remain. It was the assumptions that were wrong. There did not, nor does there, exist sufficient knowledge to mount such a narrowly targeted program," said the committee, which then proceeded to take issue with specific ways in which the VCP functions.

Its main bone of contention is that the Virus Cancer Program is a closed shop. Too few scientists participate. Too few people, all on friendly terms with each other, are in charge of handing out large sums of money to each other. It's too exclusive, too incestuous.

It was only natural that when the SVCP was formed a small group of investigators was involved—an "in group." It now represents a somewhat larger "in group" of investigators. Administratively its procedures lack vigor, are apparently attuned to the benefit of staff personnel, and are full of conflicts of interest. Because the direct targets have become fuzzy since 1964, although available funds for the program continued to grow, the program seems to have become an end in itself, its existence justifying further existence.

Virtually everyone, including NCI director Frank J. Rauscher, Jr., and John Moloney, who heads the VCP, acknowledges that there is room for improvement.

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[1] James Darnell, Vittorio Defendi, Robert A. Good, Keith Porter, James Price, Wallace Rowe, Aaron Shatkin, Chandler Stetson, Richard Tjalma, Norton Zinder, and Maurice Guss, executive secretary.

Moloney told *Science* that he thinks the idea of opening the program up to more scientists is well taken, within limits. "They have a point. We could open up. But you have to remember, this is a targeted program with specific goals, not a general granting agency." In addition to opening the shop to more scientists, by advertising contracts more widely, for example, Moloney says he was already planning to include more outside researchers on VCP review groups and that he is preparing to assemble a group of outside scientists to constitute an advisory body to his office. They will give general advice on the program and be available to advise specifically any of the various VCP divisions, or segments, as necessary. Whether such moves will quell criticism or satisfy the complaints of the Zinder committee is uncertain.

Another major issue raised in the Zinder report is the matter of contracts versus grants as a mechanism for funding science. Last June, the committee held a meeting in New York at which many persons associated with the VCP testified. Several of them were asked for their views about doing research by contract rather than by grant. In addition, the committee apparently considered the issue repeatedly as it evaluated the VCP through various routes during the course of its investigation. Most of the members of the committee do research by grant, rather than by contract, and their feeling that this is the right way to conduct research is apparent. One gets the impression that the committee is sympathetic to the use of contracts to procure specific services or materials. It makes sense, for instance, to contract with someone to produce viruses, run certain standardized tests, obtain human biopsy material, and so forth. But scientists supported by VCP contracts are also doing a large amount of what can only be called basic research in the strictest sense.

The Zinder committee seems to have two objections to this. One is simply that such studies *should* be done by grant. The other is that because the review of contracts is, in its view, not as rigorous as the review of grant applications by NIH study sections, a lot of mediocre contract work is being supported at what may be the expense of grant research.

There really are two issues. Should all basic research be done exclusively by grants? It is a question the biomedical community has been fixated on for quite a while. Some people say yes. Others, emphatically no. It is not apparent why there has to be an either-or answer, but there are very few people who really believe that there is room for both. Most of those who do are scientists who used to work on grants and now have contract support.

Should mediocre work, work that would be turned down as a grant application, be supported, sometimes virtually indefinitely, by contract? Obviously not, and here some of the recommendations of the Zinder committee surely have a place. Scientists should not, for example, sit in the room when their own contracts come up for approval. Nor, for that matter, should members of one review group have control over the contracts of another member. (VCP scientists say this procedure will be avoided under *newly* instituted regulations.) The clincher, which may be legally impossible for the NCI to implement, even were it to want to, is a recommendation to clean house and start all over again. "All contractors should be notified that their contracts will be terminated over the next 3 years."

According to Rauscher, who was responsibe for closing the portion of the board meeting at which the Zinder report was discussed, the board gave it mixed reviews. (Among the members of the board, it should be noted, are persons funded by the VCP, persons known to be antipathetic toward it, and persons in between.) There was some feeling, he says that the report focused too much on the contract versus grant issue. Others felt it failed to recognize some of the very real achievements of VCP scientists, achievement which they believe can be attributed to the fact that the resources of the program and the collaboration it fosters among groups offer something grant research does not. Others felt the report was fine.

Zinder prefers not to comment in detail because he feels obligated to maintain the confidentiality of the board and the NCI, although he says he would have been willing to present the report in open session. He will say, however, that he and the committee stand behind the report and that it was issued without a single minority opinion.

Technically, the cancer board has not yet officially received the report and may not do so until its next meeting in March. Meanwhile, discussion of details of the report will continue through a committee of the board, a committee of the Zinder committee, and a committee of the VCP staff.

Whatever finally happens to the VCP, there are members of the board who say that the Zinder committee report must not simply be accepted and then shelved. Their intention is to see that it is not, which is particularly important at a time when the Administration is putting pressure on the scientific community to do more research by contract, not less.

[From Science Magazine, Dec. 24, 1971]

### SPECIAL VIRUS CANCER PROGRAM: TRAVAILS OF A BIOLOGICAL MOONSHOT

Can basic research be targeted? The assumption that it can or ought to be has proved increasingly attractive to politicians and budget makers disenchanted with science for science's sake. Yet despite the importance of the issue, little attention has been given to a uniquely ambitious attempt at targeting basic research toward a specific goal, the Special Virus Cancer Program (SVCP) of the National Cancer Institute (NCI). The SVCP, now in its eighth year, has from the start relied heavily on the planning techniques used in space and military programs, and, for a biological undertaking, it has made similarly lavish use of resources. How well has the SVCP's moonshot approach succeeded in forcing the pace of scientific advance?

On the face of things, there has been much progress made since 1964, when the SVCP was launched with a $10 million budget. Much new knowledge has been acquired about tumor viruses and their role in causing cancer in animals. Within the last few months, the SVCP seems to have come within reach of a major goal, the isolation of viruses presumed to cause cancer in man. Discovery of one such virus was announced this July by SVCP-supported scientists at the M. D. Anderson Institute in Houston, and two more eurekas were sounded earlier this month by SVCP teams at the University of Southern California and at Georgetown University. With a tally of no less than three viruses, each announced as a probable human cancer agent by its discoverers, the SVCP might seem well on target in its goal of developing a human cancer vaccine or other antiviral magic bullet.

Although this is how the public and Congress may see it, the SVCP is held in rather lower esteem among the scientific community, particularly by those best qualified to assess the program's contribution.[1] "The SVCP has been extremely ineffective and maybe has even had a negative effect," says one distinguished cancer researcher. "I hear nothing but complaints about the SVCP. Its main trouble is that it doesn't have much of an intellectual base; it has Huebner's enormous energies, one very good person—George Todaro—but most of the contractees are pretty mediocre"—runs the verdict of a well-established biologist. An eminent West Coast virologist complains, "The SVCP is a masquerade; they make continuous proclamations of progress to justify the vast amounts of money being spent. But the nature of the program is that it excludes people who are highly critical. It has created a kind of stampede in which everyone rushes lemming- like in the same direction, and critical discussion, points of obvious contradiction, are ignored."

Several virologists blame the moon-shot-style approach of the program for what they see as its lack of evident intellectual underpinning. The present emphasis on finding a human cancer virus is regarded by some virologists as more a political than a scientific goal, designed to impress politicians and sustain the program's funding momentum. (For unless human cells differ from mouse and chicken cells, it is already clear that their genetic inheritance includes the specifications for a virus; the physical isolation of a human-derived virus will not lead to an understanding of the fundamental aspects of cancer and cell biology, which are given less attention by the SVCP.)

The success or otherwise of the SVCP is of topical interest not just because of the fanfare over the recent human virus claims, but also because of the impending reorganization of the NCI hierarchy caused by the new cancer funding. (There are also signs that the programmatic approach of the SVCP is likely to be extended to other areas of cancer research—the NCI has let an

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[1] Apart from officials of the SVCP, almost all scientists interviewed for this article asked that their names not be mentioned, many citing the risk of being denied funds, since, as one scientist said, "the NCI has a history of vindictiveness." Almost without exception the scientists quoted are both eminent and active in virology or related fields.

$800,000 contract to a firm of systems analysts to develop a "national cancer plan.") The major criticisms made of the SVCP are that it uses a wasteful method of supporting research, allows too much power to individual scientists to channel resources in a single direction, has failed to develop an intellectual base for its overall research strategy, and excludes critics and outside advice.

The SVCP has its admirers and positive achievements, but the existence of criticisms such as these, whether justified or not, shows that the program has not won the hearts and minds of the academic world. Yet the administrators of the SVCP seem to have little inkling of the dissidence in the world outside, or at least have taken no steps to cope with it. Officially, everything is running as smoothly as the arrows on the SVCP master plan, an assortment of interconnected boxes that bear labels such as "decision point" and "immunological control," and which embody the "research logic flow" for licking cancer.

The program was launched in 1964, largely on the strength of the association then coming to light between the African cancer known as Burkitt's lymphoma and the herpes-type virus named after Epstein and Barr. But the methodology and intellectual approach of the program, which until 1969 was called the Special Virus Leukemia Program, was inherited from the NCI's chemotherapy program. With the unwritten motto "Nothing too stupid to test," the chemotherapy program has handed out some $330 million since 1955 in the search for a magic bullet against cancer, yet has managed to miss discovering many of the more useful anticancer agents in current use. Nevertheless, NCI officials decided to model other aspects of cancer research on the chemotherapy program, and since the contract mechanism was an essential feature of the planned approach—how else can a planner be sure of finding others to follow his ideas?—contracts were built into the ground plan of the cancer virus program.

The budget of the SVCP had climbed to $36 million by fiscal 1971, accounting for nearly two-thirds of the funds available to the NCI's etiology division, and this year's budget for SVCP is $49 million. Formally, the SVCP is the extramural research program of the NCI's Office of Viral Oncology, but the same people, though in different capacities, operate both program and office, and the two are, for practical purposes, inseparable.

The NCI scientific director for viral oncology and chairman of the SVCP is John B. Moloney. Under Moloney serve three branch chiefs, Robert Manaker, Robert J. Huebner, and George Todaro. The names of the three branches, which, by and large, differ from one another as much as do their respective functions, are the viral biology branch (Manaker), the viral carcinogenesis branch (Huebner), and the viral leukemia and lymphoma branch (Todaro). The three branches conduct some in-house research, which is distinct in theory but not in practice from the extramural research supported by the SVCP. In fact, a fair fraction of SVCP funds are used to support industrial laboratories that serve simply as extensions of the branch chiefs' in-house research facilities. These sums seem to amount to about $5.5 million for Huebner's laboratories, $1.8 million for Todaro's, and none for Manaker's. The purpose of this arrangement is to provide operational flexibility and avoid the restrictions on NIH hiring.

The SVCP is divided into eight segments, each of which is supposed to have a specific research objective. Each segment is presided over by a chairman and advisory working panel that reviews contracts. Contracts are directly supervised by project officers, but a segment chairman may act as his own project officer, particularly for contracts that are extensions of his in-house research. The largest of the eight SVCP segments are the developmental research segment chaired by Manaker, which in fiscal 1971 controlled $10.1 million of the $31.6 million available to the program, and the solid tumor virus segment chaired by Huebner, which disposed of contracts worth $9.6 million. In addition, the branch chiefs control their in-house research budgets, which in fiscal 1971 amounted to a total of $4 million.

The total amounts controlled by each branch chief fluctuate quite widely from month to month as contracts are let, axed, or swapped, but a current estimate given by Frank J. Rauscher, scientific director for etiology and Moloney's predecessor as head of the SVCP, is that Manaker controls $9 million, Huebner $7.5 million, and Todaro $6 million. Probably few individuals in the history of biological research have had such unfettered control over so much money.

The unusual power wielded by the three branches is one focus for criticism from the academic community; but the strongest objections are to the contract mechanism of supporting research and what is perceived as the program's insulation from outside advice. "They have purposely isolated themselves from the scientific community because they have been so much on the defensive," says a virologist acquainted with NIH affairs. According to a scientist on contract to the SVCP, "The program is structurally not open. The methods by which decisions are made are designed to concentrate power with the SVCP." Although all contracts awarded by the SVCP are reviewed by the segment working groups, on which outside scientists are represented, these committees are said to function as rubber stamps for decisions already made by SVCP administrators.

Almost universal is the criticism that, for lack of outside advice and the checks and balances that govern other research programs, the principal officers of the SVCP have too much power. "I feel enormous uneasiness about the power the branch chiefs wield," says a virologist under contract to the SVCP. "It's just plain wrong. If some check cannot be put on them, then we are going to see an incredible fiasco should their judgment prove wrong." Huebner, Todaro, and Manaker each control sums of money that equal or exceed the $6 million disposed of by the entire NIH virology study section in fiscal 1971.

Almost all research supported by the NIH is financed by grants, which are allocated by a system of peer review and are not tied down to specific objectives. By contrast, the SVCP distributes all its monies in the form of contracts, which are not subject to peer review. This applies not only to clearly definable projects such as the preparation of viruses or the collection of human tissue specimens, but also to research work that, in many instances, is no different in kind from that supported by the grant system. The SVCP's exclusive reliance on contracts is considered one of its more unpopular features in the academic world. One virologist explains, "Most of the people making the top decisions at the SVCP are not top scientists. They are allocating enormous amounts of money on the basis of relatively little knowledge. But to make scientific decisions of this nature is a complicated and chancy business. The reason why the peer review system grew up is that no one individual can make these decisions intelligently."

Academic scientists point out that most of the important discoveries in cancer virology made in recent years have come from scientists working on grants, not SVCP contracts. "If you delete most of the work financed under contract to the SVCP, we would be almost as far along the road as we are now," is the verdict of one well-known virologist. "There have been lots of advances lately, but I don't know if I could assign any of them to this particular program," says a scientist intimately acquainted with the program's affairs. Another intimate of the SVCP concludes that nothing done on contract could not have been done on research grants at one-sixth to one-tenth of the cost.

Many outside scientists criticize what they consider to be the waste and poor quality of much contract research. The standard of SVCP contracts seems to have improved markedly in the last few years—many eminent virologists now have contracts with the program—and it probably no longer happens that application considered not worthy of support by the NIH virology studies section receive SVCP support. But many of the 120 contracts currently let by the SVCP still arouse less than unanimous enthusiasm.

## THREE LOOK-ALIKE BRANCHES

How does the SVCP look from the inside? To the untutored eye there is little difference in the character of the contracts controlled by the three branch chiefs, and everyone concerned gives slightly different answers. According to Rauscher, Manaker looks after resources and research on herpestype viruses, Todaro is concerned with the molecular biology of C-type viruses, and Huebner's interests are in vital serology, epidemiology, and chemical-viral cocarcinogensis. According to Manaker, "My segment is tapered towards investigations involving specifically human problems. Huebner started off with DNA viruses, then shifted to RNA viruses and has spent a considerable amount of his time looking at the natural history of cancer." Huebner's perspective is that he and Todaro do not do the same things but "leapfrog" each other; Manaker is responsible "for herpes, for a lot of resources, and for Spiegelman." Todaro says that his program puts more emphasis on basic molecular biology than the other branches do. He denies that there is any duplication between his program and Huebner's—"Huebner and I do in practice coordinate our work, and if there is any competition with Huebner's branch it is a very healthy one." Another opinion, given by a scientist close to Huebner's part of the program, is this: "There is hardly any difference in subject matter between the three chiefs. You might say Manaker was more into herpes, but it isn't really true. The real difference is one of style. Huebner feels that scientific input should come from in-house, meaning largely him, and he is exceptionally good at suggesting ideas for people to do and at seeing that his contractors communicate with each other. So his segment is really rather well controlled. Manaker manages contracts where no particular scientific input is required from him.

His contracts are a hodgepodge—if they interconnect, no one has ever seen the interconnection." The same scientist adds: "The bulk of the program is still a bunch of really worthless junk, such as injecting monkeys with God knows what and other holdovers from the early days of the program."

As far as this reporter has been able to discern, there are, in effect, two different SVCP's, neither of which has very much to do with the other except for the sharing of resources. Both programs have their good points, but both are probably the worse off for being largely closed to genuine outside review. One program is that administered by Huebner and Todaro, both of whom actively participate in the research they direct and have clear ideas of the direction in which they wish the program to go. ("The SVCP is how I feel about cancer," says Huebner.) The other program is that directed by the scientist-administrators such as Rauscher (when he was chairman), Moloney, and Manaker. All three are distinguished scientsts, though none is still active in the laboratory as are Huebner and Todaro.

Indications that the two camps operate largely independently are not hard to find. The three recent claims to have found candidate human viruses are a case in point. The candidate human cancer virus announced in July this year was discovered in the laboratory of one of Manaker's contractors, Leon Dmochowski of the M. D. Anderson Institute in Houston (the Institute's contract is at present $600,000 a year; since 1965 it has received some $2.7 million from the SVCP). Whereupon laboratories in the Huebner-Todaro program quickly proved to their own satisfaction that the virus was in fact a mouse virus that had contaminated the cell culture.

(Independent tests now make this verdict rather less certain.) Huebner is said to have obtained samples of the Dmochowski virus after writing a memorandum to Carl Baker, director of the NCI, urging that, because of the numbers of people dying daily of cancer and the research funds being expended thereon, Dmochowski not be allowed to sit on his virus. Earlier this month, scientists at the University of Southern California Medical School, which holds a $1,600,000 contract from Huebner, announced that they had released a candidate human virus after growing human cancer cells in cats. Scientists in the other camp naturally refer to the USC virus as a cat virus, but more serious evidence of rivalry was a second claim to have discovered a human virus, announced simultaneously and in direct reaction to the USC claim by scientists at Georgetown University under contract to another segment chairman, W. Ray Bryan. (Both claims were announced before appearing in the scientific literature.) Although it would doubtless be inapposite for SVCP management to try to control the release of information by their contractors, closer coordination between the two rival camps could at least establish a set of minimum criteria for announcing a human cancer virus.

A more serious lack of management control is evident in the segment working panels that are supposed to review all SVCP contracts. Rauscher and Moloney point to the existence of these panels as evidence of outside review. Most of the panels draw half of their members from the NCI staff and half from outside, but in practice it is almost impossible for the outside scientists to vote down a contract of which they disapprove. According to one panel member, whose account is confirmed by a second member of the same panel, the voting procedure on contracts is that a favorable vote may be given without explanation, an abstention counts with the majority (in effect, as an affirmative vote), but negative votes must be justified in writing. Since materials relating to a contract are often distributed only on the morning of the panel's meeting, members have to read and listen simultaneously; thus, the segment chairman, who can usually count on the votes of the NCI members, is rarely overruled. "The outside consultants are likely to end up approving things after the fact," says a former panel member, who indicates that most of the decisions on contracts are taken by segment chairmen before the working panel meets.

Another awkward feature of the working panels as founts of independent advice is the practice of having contractors as panel members. Asked how panel members. Asked how panel members were selected, Rauscher told *Science* that Huebner, for example, will ask his panel members to suggest names of outside scientists, which are then submitted for approval first to Moloney, then to Rauscher, and finally to Baker. The membership of Huebner's working panel, as approved by Moloney, Rauscher, and Baker, is as follows: Maurice Green, St. Louis University, holder of a $750,000 contract from Huebner's segment; Leonard Hayflick, Stanford University, holder of a $175,000 contract from Huebner's segment; Karl Hellstrom, University of Washington, holder of an $83,000 contract from Huebner's segment; Edwin Lennette, California Department of Public Health, holder of a $33,000 contract from Huebner's segment; Hanas Meier, Jackson Laboratories, holder of a $299,000 contract from Huebner's segment; Joseph Melnick, Baylor University, holder of an $800,000 contract from Manaker's segment; and two NCI staff members. The panel's one independent voice is Wallace P. Rowe of the National Institute of Allergy and Infectious Diseases.

The free-for-all over the candidate human cancer viruses and the setup of the segment working panels raises the question of who runs the SVCP. Several sources state that Maloney, the formal head of the program, cannot control Huebner because of Huebner's close relationship with Baker; Moloney does the best he can within the rules set by Baker, these sources say. In fact, there may be some advantage in the diversity allowed by the lack of central control. Scientists in the Huebner-Todaro camp like to depict the Manaker-Maloney-Rauscher part of the program—called for convenience the administrators' SVCP—as a ragbag of unproductive contracts based on outmoded approaches. This is closer to parody than truth; the administrative part of the program may not have the same drive and sense of direction as the Huebner-Todaro part, but the average standard of its contracts has in the last 2 years improved considerably, scientists both within and outside the program say. This is partly because of the scarcity of funds from other sources, partly because of deliberate efforts to recruit good scientists by Moloney, Manaker, and a member of Manaker's staff, Timothy E. O'Connor. Manaker's contracts now include a number of distinguished scientists such as the group under J. Tomas August at the Albert Einstein College of Medicine ($498,000), the Hanafusa team at the Public Health Research Institute of the City of New York ($159,000), George Klein at the Karolinska Institute in Stockholm ($73,000), Fred Rapp at Pennsylvania State University ($292,000), and Sol Spiegelman at Columbia University ($800,000).

The contracts under Huebner differ from Manaker's in that many of them are viewed by Huebner simply as extensions of his in-house laboratories. The unusual arrangement of Huebner acting both as an administrator and as an active scientist is a mixed blessing. On the credit side is that he is well regarded in both roles. "The real trouble with the program is that it has only on Huebner, not five or six," says a prominent critic of the SVCP. "Huebner's contracts have been more successful because he is a good manager and because he has a very good intuition, which is important in science," this critic adds.

The disadvantage of Huebner's dual role as scientist and administrator is that he is put in the position of awarding or denying research support in a field in which he has an active personal interest. He and Todaro are felt by many scientists involved in the SVCP to be more concerned with the success of their own research interests than with the welfare of the program as a whole. "Huebner is very active at trying to get the best part of every pie. I have heard him pooh-pooh things simply because they weren't part of his program," says one SVCP contractor. Many virologists are alarmed at the "unidirectional" approach of the SVCP, or at least the Huebner-Todaro part of it, which seems designed almost exclusively to provide support for the oncogene theory, a set of ideas that have been vigorously espoused by Huebner.

The publicity-tinged style of Huebner's operation, his practice of signing papers written by contractors in far-distant laboratories (in fact contracting scientists tend to add Huebner's name to their papers on a Herr Professor basis, and Huebner does often contribute significant ideas), a recent incident in which scientists in Huebner's camp (Todaro and Aaronson) risked depriving another scientist (Rowe) of priority for an important technique, and indeed the general style of Huebner's operation, have all engendered a certain sourness toward the SVCP in academic circles. Much of the hostility caused by Huebner's domination tends to fall, unfairly, on the heads of the other administrators, "The real culprit for all this is Baker," says one scientist connected with the program.

### PACE OF DISCOVERY

The flair of the Huebner-Todaro approach offers a viable and probably necessary alternative to the less *dirigste* part of the program controlled by the administrators. Nevertheless, it seems open to question, certainly by the academic community, as to exactly what the SVCP has achieved that could not have been done equally well by the grant program. Two lines of research which the Huebner-Todaro part of the program has backed heavily in the last year and a half are work on the reverse transcriptase enzyme possessed by RNA tumor viruses, which was discovered by Howard Temin and David Baltimore (neither of whom was on SVCP funds at the time, though the program supplied Baltimore with virus) and the group-specific antigens of C-type (gs) viruses first discovered by Huebner and colleagues in 1964.

Huebner states that the pace of discovery is proceeding "10 to 20 times faster than it would without the SVCP." In fact, it is probably too early to say whether the hectic pace imposed by Huebner's mehods of massed laboratory attack on a problem will really speed solutions to basic problems. For example, he and other SVCP officials claim that as a result of SVCP emphasis, "The reverse transcriptase story is worked out to an extent that would have taken 10 years under the grant program." But scientists outside the program are not so sure. Rauscher proudly claims that the SVCP made available $4.5 million of virus for researchers studying the enzyme. "It was because of this that all this terrible work appeared in the last year," says a scientist prominent in the reverse transcriptase field. Several virologists believe that under a grant program the reverse transcriptase would have unfolded at a slower but sounder pace. There seems to be greater consensus that Huebner's fantastically expensive work on viral gs antigens—to make 1 gram of antigen, which is enough to raise antibodies in ten guinea pigs, costs about $1 million—would stand little chance of being funded under a grant program and is a plus for the contract mechanism.

As for the administrators' part of the SVCP, there have certainly been successes in the past, notably the far-sighted provision for mass producing viruses before the research demand developed. The SVCP supported the work of the Henles on EB virus and mononucleosis, and SVCP contractors (including Huebner before he joined the program) helped to largely rule out DNA viruses, such as the 31 adeno-viruses (which are oncogenic in animals), as causes of cancer in man. Because of SVCP support, the number of viruses known to cause cancer in animals now totals more than 100. Yet apart from the SVCP's provision of resources, academic critics of the SVCP are not obviously wrong in claiming that nearly all of these advances could have been supported more efficiently on grants instead of the despised contract mechanism.

Administrators of the SVCP, such as Moloney, Rauscher, and Gio B. Gori, Rauscher's planning director, tend to discount all outside dissatisfaction with the SVCP by attacking the motives of their critics. Certainly the academic community harbors no natural liking for the contract mechanism and planned research of the type represented by the SVCP. But instead of trying to counter the antipathy by exposing the program to outside advice, the higher echelons of the SVCP hierarchy seem instead to have retreated to a closed world of charts and systems analyses, where cancer vaccines can be developed in five phases and three subphases. The charts, which are regarded as a harmless absurdity by the active scientists in the program, are symptomatic of the NCI administrators' divorce from reality, of their failure to provide scientific direction for the SVCP, and to straighten out its organizational confusion. But to let outside air into the SVCP, to switch some of the research-type contracts over to a grant mechanism, to start a sensible training program, and to switch more resources to basic cell biology, are approaches that seem politically foreclosed. Says a virologist close to the SVCP, "The NIH heads have tried so hard to persuade Congress that everything was ready, they are not now in a position to take the long-term view." The moonshot design of the SVCP was from the start a gamble that cancer would prove to have a short-term solution, in the form of a viral cause and a vaccine cure. But many biologists believe a longer-term view is necessary.

[From The Wall Street Journal, Monday, July 23, 1973]

## WAR ON CANCER: TROUBLE IN THE RANKS

(By Jay A. Winsten)

Dr. Winsten is a research fellow in pathology at Harvard Medical School, engaged in privately financed research on the mechanism of action of cancer-causing viruses.

President Nixon's war on cancer, launched in his 1971 State of the Union address, appears to be stalled in low gear, plagued by an increasingly bitter three-way battle for control of the $500 million of federal funds appropriated for the 1974 fiscal year.

The money itself—$140 million less than the President's original program called for by 1974—is a severe disappointment to the cancer research establishment. As a result of the budget hold-down on the expanding program, the National Cancer Institute estimates it will be able to fund only 29% of the grant applications which win approval on the basis of their quality and merit, compared to 57% in fiscal 1973.

But the most heated current issue is over the type of selection process to be used in picking the research projects to fund with the federal money. At odds in this three-way fight are university scientists, the National Cancer Institute's administrators and scientists, and the policy makers in the White House's Office of Management and Budget.

One leading U.S. scientist, appointed by President Nixon to the National Cancer Advisory Board, which oversees the NCI attack on cancer, predicts a "sizable proportion" of the board's 23 members will resign if OMB succeeds in its reported attempt to dismantle the peer review system—the network of external advisory committees which brings outside scientists into NCI's decision-making process.

### THE PEER REVIEW SYSTEM

The peer review system which gives the scientific establishment some measure of control over the spending of federal funds for cancer research, is under attack by OMB for allegedly promoting conflict of interest, inefficiency and decreased administrative accountability for federal dollars.

It functions through a network of advisory committees, called study sections, which are staffed predominantly by nonfederal scientists. Each study section specializes in a particular area of basic research and passes on the relative merits of grant applications submitted by independent researchers seeking NCI funding. Study sections, which have 10 to 15 members each, meet three times a year to review and assign priority ratings to the unsolicited research proposals. Members of the study sections, who serve four-year terms, are selected for their posts by federal scientists.

In an OMB memorandum made public by Sen. Edward Kennedy in May, these charges are leveled against the peer review system:

"The system does not assure administrative responsibility for the allocation of federal research funds by relying on the 'collective judgment' of consultants—the advisory committees—which are convened only three times a year.

"The process is largely reactive to the initiative, interest or whims of individual researchers and therefore is not readily compatible with targeted or directed research to achieve specific national objectives.

"The participatory process produces an unavoidable conflict of interest situation for the individual scientists who serve as consultants because they determine the allocation of research funds that they also receive."

The OMB memorandum suggests several alternatives for "improving" the peer review system, the first option being its "abolition." The memorandum states that any changes must "have the effect of lessening the control of the peer review process or of placing controls and safeguards on its operation."

Some scientists have expressed the fear that the attack on peer review is actually aimed at eliminating the grant mechanism for funding research. Dr.

Salvador Luria, the Nobel Prize-winning biologist who heads the new Center for Cancer Research at the Massachusetts Institute of Technology, warned in an interview that reliance on contracts as the sole vehicle for funding would lessen the chance for young scientists—not known to NCI administrators—to gain support. This, Dr. Luria said, "would have the effect of emasculating the vigor of American science 10 to 20 years from now."

According to NCI figures, 56% of the agency's research funds are currently channeled through the grant mechanism and are therefore subject to the peer review process. The remainder are distributed through the contract mechanism.

Contracts, which are also subject to review by external advisory committees, are awarded for the performance of a particular piece of scientific work desired by the Institute. Currently 93% of NCI contracts derive from research proposals developed by the NCI staff.

This system, too, has come under strong attack. In a still-confidential report, a committee of nonfederal scientists who reviewed NCI's plans for an intensified attack on cancer at the agency's request says the authority and influence of NCI personnel should be curbed. The researchers, selected for the study by the prestigious National Academy of Sciences, declared in their 24-page report that new ideas are "urgently" needed for the conquest of cancer, ideas which they said are not likely to emerge from a "highly centralized bureaucracy."

The scientific community is especially wary of the systems analysis, highly structured approach to research program planning that characterizes the new three-volume National Cancer Program Plan—the Institute's formal blueprint for the accelerated attack on cancer.

The plan defines seven "objectives" for the cancer program, each of which is divided into a hierarchy of "approaches," "approach elements," and "project areas." The plan sets priorities and funding levels for each aspect of the program. It is a five-year plan which will be updated every year in a report to Congress.

Critics who have seen Volumes I and II of the still-secret plan say they are disturbed by its managerial approach and what they say is its overemphasis on targeted research. One critical appraisal of a draft of these volumes was made last fall by an ad hoc committee of the Institute of Medicine, an arm of the National Academy of Sciences and headed by Dr. Lewis Thomas, president of the Memorial Sloan Kettering Cancer Center.

The committee's report states, "There is no question that certain types of investigations can be excellently managed by highly centralized planning, utilizing the style of systems analysis, but it seems equally clear that there are other important areas of science, necessary for the solving of cancer, in which these methods may not work.

"There are many types of cancer for which today's technologies simply do not work, and in which the way ahead for research is not at all clear," the report says, adding that research into these types of cancer "ought to involve rather less in the way of centralization. . . . What is most urgently needed for problems of this kind is an abundance of new ideas, and these are most likely to emerge from the imagination and intuition of individual scientists. It is much less likely that the administrators of large programs . . . at the center of a highly centralized bureaucracy can generate the kinds of ideas that are needed.

"The [plan] fails in this respect, by not explicitly encouraging and supporting the initiatives of working scientists involved in the system. It leaves the impression that all shots can be called from a central headquarters, that all, or nearly all of the really important ideas are already at hand, and that given the right kind of administration and organization, the hard problems can be solved. It fails to allow for the surprises which must surely lie ahead if we are really going to gain an understanding of cancer."

### MR. CARRESE'S VIEW

Louis M. Carrese, NCI's associate director of program planning and analysis, denies that the Institute seeks to control the direction of cancer research. "We do very little without going to our advisory groups," he said in an interview. He pointed out that the plan's third volume will be submitted for review to at least four groups.

Mr. Carrese emphasized the role of nonfederal scientists in determining priorities. "In all of the work that's done under grants, the scientific community in its very process of applying, reviewing itself, and assigning priorities for payments, determines what it wants to do collectively." The peer review system, Mr. Carrese says, "has nothing to do with any federal administrators whatsoever."

But peer review may go and what will replace it is uncertain. Dr. Robert S. Stone, newly appointed director of the National Institutes of Health, is quoted in the journal, Science, as saying he and other management experts "know some things about getting scientists to work productively and about structuring research." This suggests to some observers that creative managers and planners are interested in conducting their own experiments, with scientists and the cancer program as the guinea pigs.

From the opposite side of the fence, Dr. James S. Watson, Harvard's Nobel Prize-winning biologists states the case against centralized planning: "You can't plan the conquest of cancer because you don't know what it is. You hope for unplanned observations."

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[From The New York Times, Thursday, Mar. 22, 1973]

## WHEN WORLDS COLLIDE: RESEARCH AND KNOW-NOTHINGISM

(By J. D. Watson)

J. D. Watson is professor of molecular biology at Harvard and director of the Cold Spring Harbor Laboratory.

It would be nice to believe that we now possess all the basic scientific facts needed for the conquest of cancer. We could then set up timetables of expected progress, hire the required hands, and confidently expect this awful scourge to disappear from the human vocabulary. The truth, however, does not fit this fantasy and despite the stunning achievements of the modern biological revolution that has revealed the nature of the gene as well as the operation of the genetic code, huge gaps still exist in our knowledge of the fundamental biology and genetics of normal human cells much less of their cancerous counterparts.

For example, we still do not have even an order of magnitude figure for the number of human genes, nor do we have any real understanding of the signals that turn them on or off. Answers, however, to these questions as well as to many other equally fundamental problems will probably emerge over the next one to two decades if we can continue the pleasantly hectic momentum of experimental biology.

Until recently there was very little doubt about the matter. The betterment of our peoples' health is clearly one of our top national priorities, and rational attacks on the many diseases that still plague us will depend upon the emergence of new facts generated by high-level fundamental biomedical research. The events of the last several months, however, leave me with much less confidence that biology will prosper over the next decade. For the message increasingly coming out of the executive branch is that science is fine as long as the payoff is fast and our nation's scientists are skillfully channeled into work on major national problems. With the dollar weak and American products not always wanted by other nations, the word is out that we are not rich enough to do science for science's sake, but only if it generates a quick return for the buck. Unfortunately, this way of proceeding, which could at first sight seem like common sense, represents a puerile understanding of both how good science is done and how its discoveries have been directed toward human application.

We must never forget that for the most part we have little insight about the truly unknown—the world we live in is immensely complicated and on the whole its natural phenomena are remarkably unpredictable. Only after a chemical reaction within a cell has been observed, do we usually find a reason for its existence. Thus it is almost impossible to plan far ahead what the future will bring. About the best we can do is to try to bring our most intelligent and sensible minds to bear on a given problem, then let them go at their own speed and direction. This is the way the hoped-for conquest of cancer should be administered. This objective all too clearly depends upon the emergence of unexpected new discoveries and so demands the talents of the very best brains this nation possesses. They will do the best job if essentially left to their own intuition, not to those of the National Cancer Institute scientific bureaucracy who, despite the best of intentions, have no special calling for the undivined.

Yet the forthcoming governmental prescription for cancer research, if not for most other forms of medical research, ominously points in the direction of more contract money, in which the Government calls the shots, and less free grant money in which the individual scientist decides where the future may lie. All too large a proportion of this contract money will go to senior established people as opposed to younger scientists who have yet to prove themselves. Yet almost every important new discovery comes from someone under 35 and who at the moment of his breakthrough is essentially unknown to the outside world and unlikelý to be given a contract by a Government that looks with distaste on the unpredictable.

Even more disturbing for the long run will be the effects of the current edict to shut down all National Institute of Health-sponsored predoctoral and postdoctoral training and fellowship programs, as well as the career development awards which now support most of the better younger scientists in medically oriented research. If this threat is carried out, not only will all the money be tightly held by middleaged entrepreneurs, but the science itself will have for the most part to be done by an age group not noted for working into the night, which in the past has only rarely been innovative and so cannot now be expected to have a better track record.

I can, thus, only describe as lunacy a governmental policy that openly states the wisdom of choking off the supply of younger people into medically oriented research. One gets the horrid impression that somehow our nation is mounting mammoth crash programs to develop new "pampers"—not to conquer a collection of well-dug-in diseases against whom conventional approaches bounce off as if they were table-tennis balls thrown at concrete walls. Must the new American tradition be to lose our wars and call them victory? Is it possible that someday we will have our Government say that the real problem is not cancer or strokes or cononaries, but the scandalous behavior of the research scientists who lack the integrity to carry out the Government's wish for instant victory? For the sake of my children and their children, I hope not.

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[From the Congressional Record—Senate, Apr. 18, 1973]

## The Federal Assault on Cancer

Mr. Nelson. Mr. President, since enactment of the National Cancer Act in 1871, Federal dollars for cancer research have jumped from $230 million for fiscal 1971 to $432 million for 1973, with a budget proposal of $500 million for 1974. The Office of Management and Budget recently released additional funds for 1973, raising the National Cancer Institute's operating budget from $378 to $432 million.

Considerable controversy arose over the best legislative approach to increase the Federal assault on cancer: whether it should be done by an agency independent of the National Institutes of Health, with its 11 institutes; whether the emphasis should be on targeted or basic research, on contracts or grants.

The law required a 5-year plan to be drawn up, to be updated every year, for the purpose of coordinating the national cancer research effort. It was a unique concept for biomedical science, in that systems analysis was to be applied in an effort to organize a concerted cancer attack.

The plan, although apparently drawn up in three sections, has not yet been released, apparently held up in the Office of Management and Budget, and the controversy still rages over the best approach to cancer research.

The National Institute of Medicine, an institute of the National

Academy of Sciences—NAS—was asked by the National Cancer Institute to comment on the cancer plan.

A panel of nine, headed by Dr. Lewis Thomas, dean of the Yale University Medical School and incoming president of the Memorial Sloan Kettering Cancer Center in New York, prepared a critique of the cancer plan, which was completed in December 1972.

I ask unanimous consent that the panel report be inserted in the Record following these remarks, along with several news articles describing the panel's report and the still-unreleased cancer plan.

There being no objection, the material was ordered to be printed in the Record, as follows:

## THE NATIONAL CANCER PROGRAM PLAN

### I. INTRODUCTION

The National Cancer Program and the Five-Year Plan for its implementation were mandated by Congress in order to accelerate the attack on cancer. The underlying intention of the legislation, which is reflected in the design of the National Cancer Program Plan (NCPP), was to make certain that all leads toward the prevention and cure of cancer—leads currently recognized as well as those still undiscovered—be promptly and systematically pursued, and, as new successful measures become available for prevention or treatment, that these be made available for application by the nation's health care system as rapidly as possible. These objectives have had the overwhelming support of the Congress, the American public, and the President.

This Review Committee was appointed in September, 1972, by the Institute of Medicine of the National Academy of Sciences in response to a request by the Director of the National Cancer Institute that the Academy review the NCPP. Our charge has not been very explicit; we were asked to consider whether the plan is sufficiently comprehensive, balanced and clearly conceived to meet the intended objectives, assuming, of course, that it is skillfully administered. The present report is intended to serve as a preliminary overview of the plan, not as a detailed analysis of its scientific content.

It is essential that the limitations of the scope of this review be stated plainly at the outset. It is by necessary a preliminary review, since the complete, final version of the NCPP itself is not yet available; Volumes I and II have still to be reviewed in depth by the National Cancer Board and Panel, and these bodies may choose to revise the document. Moreover, Volume III, which deals with curcial matters of administrative implementation and management of the plan, is still in the process of preparation by the NCI staff and has not been available to this Committee.

For these reasons, and with these reservations, the present review is limited to a consideration of several key issues raised by the NCPP. For some of these, we believe that further clarification of the text of the plan may be needed in only a few instances do we disagree with what we interpret as the substance of the plan.

It can be stated that the Committee endorses the general intentions of the NCPP, and commends the comprehensiveness and thoroughness which have gone into the construction of the plan. We are impressed by the skill with which the plan has succeeded in organizing, conceptually, a stupendous mass of biomedical scientific material, even though we have reservations concerning the framework within which the study was conducted and the material organized.

### II. THE PLAN

Two volumes were available for review, the most important of which was Vol. II, part 1, *The Strategic Plan* which essentially outlines the research and operational strategies of the Plan. This document sets forth seven objectives which, though arbitrarily conceived, present a reasonably comprehensive and cohesive framework for understanding what is presently known about cancer. Four of the seven objectives apply to the complex and extremely difficult long-range search for the causes of cancer and methods for its prevention. The remaining three objectives are concerned with detection, therapy and rehabilitation, recognized as more short-term objectives, and perceived to become less important as information regarding the causes and prevention of cancer emerges. To achieve these major objectives, the plan presents an elaborate, structural hierarchy of lesser objectives: there are multiple "approaches" around each objective, multiple "approach elements" for each approach, and multiple "project areas" for each approach element. The ordering of the structure is conceptually that of systems analysis, and it is evident that the input of the 250 participating scientists was fitted into this framework.

Volume III, the *Program Operating Plan*, has not been completed and is therefore not available at the time of this review; as stated above, it is recognized by the Committee as probably the most critical portion of the Plan, for it intends to set out the "monitoring," "coordinating" and "implementing" features of the National Cancer Program.

By virtue of the comprehensiveness and quality of information (inputs of 250 outstanding scientists) contained in the seven major objectives, the NCPP, including the operations research "wheel," provides a good instrument for reporting the present national effort in cancer research to the Congress and the Public, and for monitoring the progress made under the National Cancer Act.

There has been some disagreement within the committee concerning our understanding of the basic intent of the NCPP. In the view of some of us, it is not intended to make a major revolutionary shift in the method of programming the wide variety of scientific work which is now done primarily on the initiative of scientists in universities and independent research institutes, but rather to lay out a total inventory of scientific areas to be covered in order to assure that no area of importance is either neglected or underemphasized from want of initiative from existing institutions. In short, it provides an assurance that nothing falls between the cracks, and that leads which hold high promise will be exploited more promptly and thoroughly than they would if no such plan were in existence. On the other side, some of us believe that the systems analysis approach may represent the underlying philosophy of the whole program, and may be extensively used, even become the predominant mode of research management. In particular, we are concerned lest the categories established in the "wheel" become rigid budget categories, which then establish correspondingly rigid priorities. There is no question, of course, that certain types of investigations can be excellently managed by highly centralized planning, utilizing the style of systems analysis, but it seems equally clear that there are other important areas of science, necessary, for the solving of cancer, in which these methods may not work. This matter is considered in the section which follows.

## III. THE CENTRALIZATION ISSUE

The NCPP tends to give the impression that all cancer research is pretty much the same sort of activity, and that all of it can be run on highly centralized basis, with "targeted" programs throughout; the way ahead is uniformly clear, and all needed lines of research can be clearly envisioned in an orderly progression. This impression is perhaps unintended, since the NCPP itself, in the introductory section of Vol. II, discusses the major dilemma of cancer, which is that so much of the crucial biological information, needed for solving most varieties of cancer, is totally lacking.

It seems to us that human cancers can be classed under two principal headings, depending upon the relative effectiveness of the therapeutic technology which is either available today or likely to be developed in the near future. The terms *Feasibility* and *Prefeasibility* can be used to indicate the two major sets of problems.

*Feasibility* denotes the current situation in the prevention and cure of the kinds of cancer in which a highly effective, decisive technology is at hand, with real prospects for its continuing development. In this category belong acute childhood lymphatic leukemia, Hodgkin's Disease, certain other lymphomas, choriocarcinoma, Wilms' tumor, carcinoma of the cervix, and some types of skin cancer.

*Prefeasibility* denotes the situation for the kinds of cancer in which today's therapeutic technology is unsatisfactory, with little or no evidence of progressive improvement in recent years, and no immediate prospect for change unless some completely new information becomes available. This group includes most of the solid malignancies of adult life, including cancer of the brain, breast, lung, gastrointestinal tract, liver, and bone. This is not to say that all of these represent hopeless problems today; indeed, as the NCPP points out, there are effective things to be done for many on this list, especially when they are detected early, but they share in common an unacceptably high mortality and a general lack of discernible prospects for major change in the immediate future.

Basically, the success of today's technologies depends largely on whether all the neoplastic cells in a particular cancer can be extirpated. The remarkable success in the treatment of cervical cancer is due to the relative ease with which this tumor can be detected early and completely removed by surgery in the majority of cases. The rapidly dividing cells of acute lymphatic leukemia are especially vulnerable to chemotherapeutic drugs, and can be chemically extirpated. For these and a limited number of other cancers, there are highly effective forms of treatment, with excellent prospects that further improvements will be achieved within the near term by accelerated research. Moreover, the direction which this research should take is reasonably clear. The work can best be done if the investigators are centrally organized, with general agreement as to who will be doing what, and when.

The situation in the *Prefeasibility* group of cancers, which actually comprise the considerable majority of human cancers, seems to us altogether different. For example, glioblastoma multiforme, a common neoplasm of the brain, is essentially incurable; it is not cured by surgery even when detected very early, nor is its growth reversed by irradiation or chemotherapy. Currently, something between 20 and 30% of women with breast cancer (the actual figure is arguable) will die from this neoplasm regardless of when it is detected and what form of therapy is used. The mortality from bronchogenic carcinoma of the lung is extremely high, and today's treatment is almost entirely unsatisfactory. And so on. There are many types of cancer for which today's technologies simply do not work, and in which the way ahead for research is not at all clear.

We suggest that the organization and management of research on cancer in the *Prefeasibility* area ought to involve rather less in the way of centralization, and rather more of a tendency toward decentralization. What is most urgently needed for problems of this kind is an abundance of new ideas, and these are most likely to emerge from the imagination and intuition of individual scientists. It is also demonstrably true that when groups of scientists are well organized in collaborative, cross-disciplinary research they can provide a rich source of imagination and new ideas. But it is much less likely that the administrators of large programs, or committees of administrators, at the center of a highly centralized bureaucracy, can generate the kinds of ideas that are needed.

It seems to us a defect of the NCPP that the enormity of our ignorance about cancer receives less emphasis than it merits. Much is said about the lines of research that appear most promising today—virology, cellular immunology and genetics, for example—but too little acknowledgement is made of the genuine possibility that any or all of today's leads, including all of those proposed by the 250 scientists in the Airlie House Conference, could turn out to be the wrong leads.

The NCPP fails in this respect, by not explicitly encouraging and supporting the initiatives of working scientists involved in the system. It leaves the impression that all shots can be called from a central headquarters, that all, or nearly all, of the really important ideas are already in hand, and that given the right kind of administration and organization, the hard problems can be solved. It fails to allow for the surprises which must surely lie ahead if we are really going to gain an understanding of cancer.

The Committee believes that this defect may be less real than it appears, and that it may in fact be largely a problem of language interpretation. The plan certainly leaves open the possibility of flexibility in management, and makes it clear that much of the science can be done with decentralized instrumentalities, by individuals and groups working independently in institutions supported by one or another variant of the grant-in-aid mechanism. It is obvious that a balance of some sort must be struck between total reliance on a centrally managed scientific plan, which is perhaps appropriate for the development of leukemia chemotherapy, for example, on the one hand, and total reliance on completely decentralized, autonomous instrumentalities on the other. From our reading of the plan, we share the impression that the NCPP pushes the balance too far in the direction of centralized scientific planning and imposes too great a risk of bureaucratic rigidity. If, as we hope, this is not the intention of the NCPP, the impression could be rather easily dispelled by some changes in language.

### IV. THE ISSUE OF BASIC RESEARCH

In this section, we intend to avoid the conventional doctrinal dispute over which is better or more productive in the short or long run, "pure" or "basic" research without a recognizable target, or "applied" research directed toward a clear, approachable objective. This is not the issue here. The NCPP provides for an abundance of research fields, some at the most profound levels of modern biology, and the documents contain sophisticated presentations of the need for new information from such fundamental sources.

What we mean by basic research, in the present context, is the sort of research which is, to begin with, important for the cancer problem, but is done by investigators who are not labeled as cancer researchers, not based in departments or institutions concerned with cancer, and who may not even recognize that their research preoccupations are relevant to the cancer problem. Such scientists may fail to obtain support under the new cancer initiative simply because their research applications will never reach the NCI through the present NIH system.

This is really a technical problem, not an argument about policy. The NCPP presents with admirable emphasis the need for new knowledge in certain specified fields for biomedical science: cell biology in general, virology, immunology, and so forth. At this level, it makes little difference whether an investigator recognizes himself as a cancer scientist or not, provided that his work is penetrating, sophisticated and of high quality. It would be a dead loss to the cancer effort if research of this kind were to go without support because of fund shortages in the other institutes of NIH—The Institute for General Medical Science, for example, which is chronically underfunded.

What is needed is some better sensing mechanism within NIH for the recognition of the basic science projects which are essential for the ultimate success of the cancer program. Obviously, the totality of biological science cannot be supported by the cancer program. Our suggestion would be for the NCI to prepare a formal listing of the science areas considered to be relevant, regardless of the title of a project or the individual scientist's orientation toward cancer. Such a finite and relatively precise list might, in fact be lifted straight out of the NCPP itself, with a few modifications. We would propose the following areas: *DNA replication, the cell cycle, regulation of transcription, regulation of membrane assembly and function, cell differentiation, regulation of protein synthesis,* and all aspects of *cellular immunity.* Research along these lines should be supported with cancer funds irrespective of the cancer-orientation of the investigator or his institution, and irrespective of the systems used in the research (i.e. eukaryotic or prokaryotic cells, normal or cancer cells, virus or bacteriophage, etc).

The list should be regarded as flexible, subject to additions or changes depending on the progress of cancer biology itself. To give an example, a few years ago very few people recognized that the delineation of the cellular immune mechanisms in homograft rejection had opened a productive and relevant area for cancer research. The NCPP should possess sufficient flexibility and agility so that new fields with this sort of promise can be recognized early, and developed quickly.

### V. THE ISSUE OF CANCER CONTROL AND HEALTH CARE

The text of the NCPP is in need of some clarification with respect to the meaning and content of Cancer Control, which is one of the assigned responsibilities of the National Cancer Program under the Act. This part of the program, and the clinical programs envisioned for the Comprehensive Cancer Centers should be differentiated from the ordinary day-to-day requirements for clinical care which cancer imposes on the nation's health care system as a whole.

In its present form, the NCPP could easily be misconstrued as a plan for a *total* attack on cancer, including the treatment of all cancer patients, which would imply a capacity to deal with the enormous problems of inefficiency and inequity now confounding the health care enterprise throughout the country. It is obvious that the NCI was not assigned such a mission, and is in no position to carry it out if it were. The NCCP is a research plan, not a program intended for implementation of the nation's health care delivery system. It seems to the committee most important that this point be made expicitly and abundantly clear in the NCPP itself, perhaps with a recommendation that such a total strategy be developed under the leadership of HEW, but not in NCI. The Secretary of HEW has under his supervision other agencies of government which spend vastly more in health activities than all of NIH combined—the Social Security Administration (Medicare), the Social and Rehabilitation Service (Medicaid), and the Health Services and Mental Health Administration.

If the Congress and public were to conceive of the NCPP as a total plan designed to mobilize all the institutions, professional practitioners and technicians of our society into a coordinated and rationalized "War on Cancer", it seems unavoidable that the outcome would be the deepest disillusionment. An attempt to define as clearly as possible the limits of this mandate should be part of NCPP.

On the other hand, even under the limited mandate of Cancer Control, providing for research and demonstration but not general health care, the program presents great opportunities for the NCPP. Thus, improvements in today's methods for the education and training of all the health professionals in the cancer fields, technicians, nurses and physicians, would inevitably result in an upgrading of the quality of cancer care. Similarly, there are obviously high stakes in new programs for the education of the public.

If, as an early outcome of the NCPP, the country were to be provided with significant numbers of health professionals, trained in the use of specialized techniques and facilities, this would surely be recognized as a valuable product, solid and highly visible. It is in the Control Program, particularly the activities related to cancer detection, diagnosis and therapy, that the plan offers the greatest promise, in the short term, of decreasing cancer morbidity and mortality. In this area, targeted research is justified. There is, however, considerable ambiguity, and therefore some confusion, in the presentation of this program in the NCPP. It needs more emphasizing that this activity will require high standards, rigorous research and evaluation and careful, detailed planning, if th emethods of bringing today's technology to the detection, diagnosis, treatment and rehabilitation of cancer patients are to be improved.

## VI. THE ISSUE OF GRANTS VS. CONTRACTS

In a sense, this problem really lies beyond the scope of the Review Committee, since the available volumes of the NCPP contain no detailed presentation of future policy on the relative use of grant or contract mechanisms; it is possible that further information on this point will be contained in the still-unfinished Volume III.

However, the issue has continued to arise throughout our discussions, particularly in connection with the problem of balance between Centralized and Decentralized planning. It is our view that the need for balance between grants and contracts is a part of the same problem, and we therefore wish to make the following comments.

The NCI is unique among the institutes of NIH in its extensive use of contracts (50% or more of its funds) for carrying out its scientific mission. The reliance on contracts has been steadily increasing in recent years, and there is apprehension within the scientific community that if this trend continues, the traditional project grant system for the support of research programs generated spontaneously within the scientific community and adjudged by peer review may be virtually supplanted by the contract mechanism. The arguments in favor of contracts are chiefly administrative: the initiatives for research come out of the central planning authority, there is more efficiency in the control and coordination of research programs and decisions can be implemented with greater speed. In recent years, the contract mechanism has been used rather widely by NCI in extension of its own, intramural scientific activities, some of these involving quite basic (rather than applied) research programs. This practice has been criticized publicly on the grounds that the peer review system, which sets the standards of scientific quality elsewhere in the research support system, is not applied with the same rigor and visibility in the contract program.

The NCPP should deal more explicitly with this problem, and ought to provide new guidelines for the situations in which grants or contracts will be the mode of research support. The review Committee believes that a balance between these mechanisms must be established and maintained.

There are particular kinds of research and development for which the contract system is ideally suited, principally in the *Feasibility* area. These would include large-scale testing or confirmation of therapeutic concepts, or the accumulation of large-scale epidemiologic information, or the rapid and efficient procurement of certain products needed for research (virus stocks, cell lines, enzymes, special isotopes, animal lines, new instruments, etc.). There is need, however, for a more effective, generally visible, and uniform review process for the regulation of the contract system in order to assure standards of excellence throughout.

The grant-in-aid system, with open competition among scientists and peer review by scientists, should be retained and strengthened by the NCPP. These mechanisms, which have grown to the stature of established traditions over the past two decades, are held in high regard and trust by the scientific community; it is general belief that they work well for the benefit of science. Measures must, however, be devised to increase the efficiency and speed of the project grant system. Very likely, there will continue to be a trend toward larger and more comprehensive projects, on the order of today's "program-project" and "center" grants. The committee believes that consideration should also be given to even larger packages, in the form of total institutional support ("institutional agreements") for cancer research programs. This trend toward grants of larger scale serves to stimulate more coordination and collaboration between scientists from different disciplines in the same institution, and seems to us both timely and desirable.

The role of the in-house scientific staff of NCI in decisions about research on the national scene, particularly with respect to contracts, has been actively discussed by the Review Committee. We do not have a single point of view about this complex issue. It is, on one hand, clearly beneficial to have a high degree of scientific expertise immediately available for participation in policy decisions. On the other hand, there are obvious risks for the future in assigning excessive authority for decisions affecting the national course of science to a relatively small group of investigators, with their own favorite ideas about the way to go.

Two members of our Committee have suggested that the "intramural research NCI" should be separated from the "administrative NCI", and one has proposed that the intramural scientific effort should compete for its budget with other cancer institutes and centers across the country. We are agreed that the mechanisms for continuing external review of the in-house NCI research programs need considerable strengthening. The issues are complicated, and it is hoped that a future version of the NCPP will give consideration to the problems raised.

## VII. THE ISSUES OF INSTITUTIONAL STABILITY AND INSTITUTIONAL DIVERSITY

Apart from NCI itself, the principal resource to be generated by the NCPP is the national network of medical schools, universities and independent cancer institutes. Many of these institutions are currently under severe financial strain, particularly the country's medical schools, and the continuing stability of these institutions presents a serious problem. Obviously, the National Cancer Program cannot be regarded as a new source of fiscal stability, but some thought must be given to the possible hazards of increased stability as an effect to the NCPP. The institutions will be required to increase their research staffs, and new buildings will be constructed to house the facilities for expanding research. Thus, the institutions will be taking on new, long-term commitments for faculty support and plant maintenance, without a corresponding assurance of long-term continuity of outside support. The NCPP does not deal adequately with this general problem.

The Committee does not have any global solution of its own. The problem of faculty support might be alleviated, to some extent, by a considerable expansion of long-term, renewable stipends along lines of today's Career Development Awards. Perhaps an entirely new program of Senior Fellowships should be devised. The Career Award program, once adopted by NIH but then quickly terminated, should be reexamined for its possible usefulness at this time; the experience of the American Heart Association and American Cancer Society with tenure investigatorships would indicate that this method of recruiting and retaining distinguished scientists is a good one.

The financial dilemma of the medical schools, as institutions, poses genuine hazards for the future success of the National Cancer Program. These institutions will be placed under new stress because of the present requirement for matching funds for the construction of cancer facilities, and they face even greater demands for the future maintenance of these facilities. It might be well to consider a greater degree of flexibility in the requirement for institutional contributions to such facilities, and some better ways to guarantee long-term support.

The Committee discussed the possible advantages of the British Medical Research Council Units, as one way to relieve the financial pressures on institutions. Under this mode of operation, the government would assume total, long-term responsibility for the construction, staffing and maintenance of new facilities in the universities and medical schools. Some experimentation along this line should be considered for the future.

We believe that the critical importance of institutional diversity does not receive sufficient attention in the NCPP. We believe that there will be an increasing need for the widest variety of institutions, ranging from small clusters of individual scientists to huge, coherent organizations totally devoted to cancer research. In many instances such institutions ought to have considerable autonomy, even if their research directions are inconsistent with the views of the central planners. Ways must be devised to foster the development of this diversity, and, at the same time, to encourage coordination of their collective efforts and, above all, to assure that the atmosphere in each will stimulate good science.

## VII. THE ISSUE OF RESEARCH TRAINING

The NCPP perceives the urgent need for more professional manpower during the next decade, if the mission of a major expansion of the national research effort in cancer is to be successful. It is obvious that this will require a considerabe expansion of training programs to produce the scientists needed for the future. The only arguments are around the question as to what kinds of training programs, for what kinds of scientists.

Here, as in our consideration of other problems in the NCPP, it seems useful to resort to the *Feasibiilty—Prefeasibility* categories. For ongoing and future research in the *Feasibility* area there will be increasing needs for professionals at all levels. The field of cancer detection will require technical manpower for various cytological, biochemical and raliological procedures. The disciplines of surgery, radiation therapy, anesthesiology, pharmacology, medical oncology and rehabilitation medicine will need more trained specialists and more technical support. The expanding field of chemotherapy, with the increasingly complex technological requirements involved in patient care, will require its own cadre of specialized personnel. Training programs for these purposes are probably best located in the institutions dedicated primarily to cancer research; the proposed Comprehensive Cancer Centers should be of great value for this mission.

There is, however, another important area of manpower need for which training programs must be provided on an amplified scale, and for which the optimal locations for training may be quite separate from cancer research units. As has been pointed out in the NCPP, and in an earlier section of this review, there are a number of basic science areas on which the future of cancer research may very well depend—*molecular genetics, cellular immunology, membrane regulation*, etc. The NCPP does not make provision for training programs in such areas. Indeed, the scientific areas recognized in the present version of the plan seem extremely limited; pharmacology heads the list, followed by chemistry and epidemiology, but there is no mention of the equally urgent needs for training in other fields of basic science.

It must be recognized that some of the best opportunities for training at this level may be in departments of medical schools and universities which are not themselves committed to cancer research. This must be faced squarely, and training programs in such areas must be supported. The solution to the cancer problem may require, at some future date intensive research by scientists skilled in problems dealing with cellular immunology or cell membrane assembly, for example, and it is mandatory that the training of such people be started now, in the laboratories where the best work in these fields is currently in progress.

The committee believes that training for cancer research should also involve some exposure to broader aspects of the cancer problem, and it will be important to encourage the development of interdisciplinary collaboration in training. Wherever possible, clinical and basic science trainees should have opportunities to interact with each other; ideally, research trainees should be exposed to problems in human cancer during their period of training in a particular area of basic science.

### IX. THE ISSUE OF CONTINUING REVIEW OF THE NCPP

The President's Cancer Panel and the National Cancer Board should have a strong and continuing policy input into the way the NCPP is implemented. This should include their involvement in the preparation of the annual report and renewed 5-year projections, and their supervision over all major operational decisions of the NCI. It is foreseeable that when a breakthrough occurs that might shift the focus of the program within the seven major objectives, readjustments of the allocations scheme among these objectives will become necessary.

When this takes place, the NCPP (Vol. 11, 5.2.2.) provides that the NCI may make "additional investments . . . whenever warranted by significant opportunities and leads", and may also "reduce investments whenever warranted by factors such as completion of the work, achievement of sufficient information, change in priorities due to shifts in the scientific base, etc."

When budget readjustments are minor, they should probably be made by administrative action in NCI. However, when these trade-offs involve alterations of strategy of significant magnitude, the Panel and Board should provide oversight. We assume that this will be the case, but we believe that the provision for Panel and Board involvement in NCI decisions, at all crucial operational stages, should be more explicitly stipulated in the text of the plan. In effect, this assures the participation of "outside" reviewers, with a primary responsibility for determining that there has been a major breakthrough, and that intensive exploitation and a shifting of funds are appropriate.

There may be a need for another kind of periodic "outside" review by a highly competent group, completely extramural to NCI, with enough time to conduct site visits to NCI headquarters and to selected institutions in which major investments are being made by NCI. The individuals chosen to carry out such periodic operational reviews should represent a variety of backgrounds and skills. We are not prepared to recommend how they should be chosen, nor to stipulate their functions in detail, but we are unanimous in the view that formal mechanisms for such review should be established.

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[From the Washington Post, Apr. 17, 1973]

## Cancer Plan Accused of Stifling Creativity

(By Stuart Auerbach)

In a still secret report, the National Academy of Science's Institute of Medicine says a government plan to conquer cancer will stifle the scientific creativity needed to find cures for the disease.

The institute report accuses the federal cancer planners of trying to direct all research from Washington when what is really needed "is an abundance of new ideas . . . (that) are most likely to emerge from the imagination and intuition of individual scientists."

The plan on how to conquer cancer, the institute report says, "leaves the impression that all shots can be called from a central headquarters; that all, or nearly all, of the important ideas are already in hand, and that given the right kind of administration and organization, the hard problems can be solved.

"It fails to allow for the surprises which must surely lie ahead if we are really going to gain an understanding of the cancer."

The report, requested by the National Cancer Institute, was written by a nine-man committee of cancer experts headed by Dr. Lewis Thomas, dean of the Yale University Medical School and the incoming president of the Memorial Sloan Kettering Cancer Center in New York.

Specifically, the committee looked at the first two volumes of the National Cancer Program Plan required under an 18-month-old law setting up an intensified national war on cancer.

The plan itself is long overdue and sources say it is undergoing revision by the White House's Office of Management and Budget.

Louis Carrese, who developed the plan for the National Cancer Institute from the recommendations of 250 scientists, said "a lot of changes" were made as a result of the Institute of Medicine review.

Carrese, a systems analyst who is trying to use that process to direct biomedical research acknowledged that some members of the committee "will think we didn't make enough changes."

He denied that the plan aims to control all cancer research from Washington and said that "quite a few word changes—jargon changes—that were worrying the committee" should erase the impression.

Although the Institute of Medicine report says that some of the plan's "defects" can be corrected with language changes, it points to a more substantive problem in the way science should be managed.

"The National Cancer Program Plan," the committee says, "pushes the balance too far in the direction of centralized scientific planning and imposes too great a risk of bureaucratic rigidity."

Moreover, the committee says that the cancer plan doesn't place enough emphasis on "the enormity of our ignorance about cancer."

"Much is said about the lines of research that appear most promising today—virology, cellular immunology and genetics, for example—but too little acknowledgement is made of the genuine possibility that any or all of today's leads . . . could turn out to be the wrong leads."

Many of the new leads for curing cancer, the Institute of Medicine committee feels, will come from scientists not in the cancer field—indeed from scientists "who may not even recognize that their research preoccupations are relevant to the cancer problem."

"Such scientists may fail to obtain support under the new cancer initiative simply because their research applications will never reach the NCI through the present National Institutes of Health system."

This point is especially important now since President Nixon has cut the budgets of all the institutes at NIH with the exception of his two favored health projects—cancer and heart disease.

The National Institute for General Medical Science, the committee report points out, deals with basic research that could have important implications for cancer. This institute is chronically underfunded.

"What is needed," the committee says, "is some better sensing mechanism within NIH for the recognition of the basic science projects which are essential for the ultimate success of the cancer program."

The committee says that research involving the replication of genetic material, the behavior of cells and the way their membranes are assembled, the synthesis of proteins and cellular immunity should all be supported with cancer funds.

The committee report also calls for the continuation of the grant system, where scientists receive funds for research projects that are judged by other scientists, over the hiring of labs for specific projects under contracts.

It also opposes the cutting of training grants, as proposed by President Nixon in his 1974 budget. These grants, it is asserted, are needed to insure the continued flow of scientists into research.

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[From the Boston Globe, Mar. 7, 1973]

## Nobel Winner Calls Nixon's Medical Research Policy "Lunacy"

(By Richard Knox)

Washington.—Prof. James D. Watson, the Nobel Prize-winning Harvard biologist, yesterday told the U.S. Senate Health Subcommittee that the newly launched Conquest of Cancer effort will be "a massive fraud" if the Nixon Administration implements its plans for the spending of medical research funds.

The mild-mannered scientist, whose discoveries of the structure of the DNA molecule made most modern cancer research possible, used the word "lunacy" to describe the Administration's research spending plans.

Delivering the strongest statement heard thus far against the government's National Institute of Health budget proposal, which was revealed January 29, Watson focused his criticism on two policy decisions:

—A cutback of basic laboratory research in favor of "targeted" research designed to apply what is already known.

—A plan to eliminate all Federal support for training new biomedical researchers, on the assumption that young scientists-in-training should find support elsewhere.

Taken together, Watson said, these decisions will insure that additional funds will be wasted rather than leading to the hoped-for cancer conquest.

"Must the new American tradition be to close our wars and call them victories?" Watson asked. "Is it possible that someday we will have our government say that the real problem is not cancer or strokes or coronaries but the scandalous behavior of research scientists who lack the integrity to carry out its government wish for instant victory."

Watson's testimony capped a day of hearings, chaired by Sen. Edward M. Kennedy, which featured criticism of the government's biomedical research policy by Dr. Michael de Bakey, the Houston heart surgeon and Dr. Lewis B. Thomas, dean of Yale medical school. The Administration's side will be presented tomorrow by Casper Weinberger, Secretary of Health, Education and Welfare.

Watson, one of the foremost investigators of a possible cancer-virus link, said that the Administration has a "puerile understanding of both how good science is done and how its discoveries have been directed toward human application."

He argued that "targeted" research, "in which the government calls the shots," ignores the fact that "most research advances have resulted from allocating grant money in which the individual scientists decides where the future may lie."

"All too large a proportion of this contract money will go to senior established people as opposed to younger scientists" added Watson.

"Yet almost every important new discovery comes from someone under 35, who at the moment of his breakthrough is essentially unknown to the outside world, so is unlikely to be given a contract by a government that looks with distaste on the unpredictable."

Watson was 25 when he did the work on DNA structure that won him the Nobel Prize along with Francis Crick and M. H. F. Wilkins.

The elimination of training grants, post-doctoral fellowships and career development awards (which allow young scientists to pursue their own leads), Watson continued, will lead shortly to a shortage of creative young scientists with the stamina needed to devote themselves entirely to basic research.

"All the money will be held by middle-aged entrepreneurs," he said, "but the science itself will have, for the most part, to be done by an age group not noted for working into the night."

Likewise, Watson added, under questioning by Sen. Kennedy, the Administration's assumption that young scientists can find money elsewhere to be trained will lower the quality of research and shorten the span of creative years in which they can devote themselves solely to science.

"Young researchers will have to work their way up through science," he said, "and you can't do good research after driving a cab for eight hours."

Watson said that "not one of my colleagues believe the Administration is following the proper course in spending cancer research funds, but most "don't have the fight in them."

"You mean they think the government is saying, in effect, 'be quiet or you'll get cut even more?' " asked Sen. Kennedy.

"Yes," answered Watson. "They have the feeling that this isn't the time to speak out."

Watson is a member of the National Cancer Advisory Board, which is supposed to advise the President on how to spend Conquest of Cancer funds.

However he said that policy decisions are being made elsewhere. "The advisory board is not a body that's ever going to be a cohesive group," he said. "They'll just hand out press releases for five years about how great everything is going."

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[From the Science magazine, Mar. 30, 1973]

## NATIONAL CANCER PLAN: THE WHEEL AND THE ISSUES GO ROUND

(By Barbara J. Culliton)

The national cancer plan may soon be released; then again, it may not. The people at the National Cancer Institute (NCI) who are in charge of such things say that they would like to make the plan public as soon as possible. There are two problems.

The first seems to be that the people at NCI are not really in charge at all. People in the Office of Management and Budget (OMB) and in the White House are. Strictly speaking, the National Cancer Program Plan is a document the NCI submits to the President, who will then transmit it to Congress. The word is that certain OMB staff members are unhappy about parts of the first two volumes of the cancer plan and their unhappiness is forcing a delay. This is hard to prove one way or the other because OMB people will not talk about such things. However, it is certain that, without their approval, the NCI cannot make its plan public. When OMB and the White House are ready, they will release it.

The second problem in getting the cancer plan into the open, so that the entire scientific community can see for itself what the cancer crusade is all about, is that the third volume is not exactly finished yet. This is the volume that NCI leaders say is the most important because it will tell how the cancer program is going to be run, not just this year, but for the next 5—a 5-year plan to be updated every year. Louis Carrese, associate director of NCI for program planning and analysis, describes the third volume as an "operating document, perhaps a manual." It will be completed soon, but that does not mean that it will be available to the public soon. It, like volumes 1 and 2, will have to wend its way through channels.

The cancer plan is a unique document in biomedical science, in that it is a tangible expression of this country's first attempt to wipe out a disease through a coordinated effort on a national scale. The sheer magnitude of the program for the conquest of cancer is unprecedented in biology.

The national crusade against cancer is grounded in the belief that cancer is susceptible to an organized attack. This presumption troubles many scientists today, as it has from the beginning. Their conviction that there is a lot of science that just cannot be targeted simply will not go away. The expectation that the cancer crusade would be backed by virtually unlimited money is also proving to be a troublesome presumption. Although it is perfectly true that there is more money for cancer research than for any other kind, it is apparently not true that the coffers of the NCI are overflowing.

As of this writing, the NCI is still operating with $378 million—its budget level for fiscal 1972. There is talk of a special presidential action to raise the level for 1973 to $432 million, as originally planned, but it has not happened yet. Meanwhile, of course, those anticipated extra funds are not available.

Thus, the situation is not an entirely happy one. The story of the cancer plan is, in ways, a reflection of the ups and downs within the national cancer program as a whole.

### PLAN IS FOR EVERYBODY

In a recent interview with *Science*, Carrese talked about the plan. Whom is it for? For everybody. The plan, he says, is supposed to be "meaningful" to the lay public, the Congress, the scientific community, and the people in the OMB. At its heart is a single goal—"Develop the means to reduce the incidence, morbidity, and mortality of cancer in humans." To achieve it, the NCI has laid out seven objectives, which "reflect the aspects of the disease in man." The first is cancer prevention; the seventh is rehabilitation of the cancer patient. The others range from basic research to therapy. To achieve each objective, there is a series of "approaches"; for the approaches, a set of "approach elements," and, to refine the task further, a host of 'project areas." It is at the level of a project area that actual research comes in.

Carrese emphasizes again and again that one of the most extraordinary features of the plan is its authorship. Out of a pool of 1000 scientists, the NCI asked about 250 to meet in small groups to decide what the cancer plan should say. From meetings held at Airlie House, a retreat in the Virginia countryside, they generated 40 reports, each of which talked about cancer from a different angle. From these, Carrese and his staff, with the advice of the chairman of the various groups, put the plan together.

The first steps for the creation of a national cancer plan were taken in the fall of 1970 by Carrese and Carl Baker, who was then the director of NCI. Groups of scientists first began meeting in the late fall of 1971, so by the time the National Cancer Act of 1971 became law that December, the foundations of the master plan had already been laid. (The law required that there be a plan, as Carrese and Baker anticipated.)

Carrese is adamant about the flexibility of the cancer plan. "Its purpose is not to direct daily research; nor is it meant to exclude new ideas." Nevertheless, a lot of the people who have had access to the plan or who have heard a lot about it are pretty uneasy. Certainly one reason for this is that the plan, to a large extent, is written in the jargon of a systems analyst.

Carrese is a systems analyst who has made a career of trying to adapt the traditional concepts of systems analysis to the process of biomedical research. He and Baker shared the view that systems analysis could be appropriately modified, and, in the April 1967 issue of *Management Science* they described their approach in a paper entitled, "The Convergence Technique: A Method for the Planning and Programming of Research Efforts." "Planning," Carrese says, "is not strange to science. Some of the most detailed plans are called experimental designs. I don't know a single scientist who arrives at his lab not knowing what he is doing."

According to Carrese, the cancer plan not only lays out the scientific and medical problems to be solved but does so in a way that allows administrators to know at a glance what is going on. He points out that the plan is designed to have "something for everybody" and that what you see in it depends upon how you look at it. In that regard, he says that he can look at it and tell in dollars and square feet of space how much effort is being committed to research on cancer prevention, causation, or rehabilitation.

To make the whole thing graphically clear, the plan has been drawn up in the form of a wheel that sets out the objectives and approaches of the cancer program. It hangs on the wall in dozens of laboratories and offices throughout the National Institutes of Health (NIH) and, depending upon the wall, is meant to be taken quite seriously, or, alternatively, as pop art.

The systems analysis approach, so foreign to most scientists, bothers many of them, and there is growing concern that the emphasis on supporting only those things that fit into the cancer *program* will lead to unhealhty rigidity. NCI officials, of course, insist such fears are foolish.

One "official" reaction to the first two volumes of the cancer plan comes from a committee of the Institute of Medicine, a part of the National Academy of Sciences. (The NCI asked the institute to review the plan last summer.)

Under the chairmanship of Lewis Thomas, who has recently resigned as dean of medicine at Yale to become president of the Memorial Sloan-Kettering Cancer Center in New York, a committee of nine[1] spent moest of their fall weekends conducting the review in order to meet a crash deadline of 1 December. They read and reread the plan, admitting that the systems analysis jargon made the going rough in spots. (Carrese says most of that jargon was deleted from the final draft.) They interviewed many of the principals involved in the creation and execution of the plan. And they looked at the 40 reports from which the plan was synthesized. Then they summed up their feelings about it all in a succinct, 23-page report, which, like the cancer plan itself, remains officially a confidential document, although numerous copies are in existence.

By prior agreement with the NCI, the institute will not release its critique until the plan itself is unveiled. Many members of the review committee concede that they are not particularly happy about the necessity for such confidentiality this long after the review's completion.

On first reading, the institute's review sounds rather innocuous. It is written in language that is neither abrasive nor laudatory, and it sounds in places as if its authors are merely politely asking questions that they are sure can be answered. A second or third look can leave one with the impression that the reviewers' opinion of the plan, and of what it represents, is scarcely as neutral as it first seemed.

In their introduction they say, "We are impressed by the skill with which the plan has succeeded in organizing, conceptually, a stupendous mass of biomedical scientific material, even though we have reservations concerning the framework within which the study was conducted and the material organized." The framework, of course, is one which assumes that research can be effectively programmed on a massive scale. Throughout their review, the authors explicitly or implicitly question this.

They find the plan "reasonably sound" as an inventory of the problems of cancer, an "assurance that nothing falls between the cracks." Carrese points out, in this regard, that the identification of rehabilitation of cancer patients as a primary objective emerged as a result of the comprehensive planning. Rehabilitation has not received much attention in the past.

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[1] Lewis Thomas, Yale; David Baltimore, Massachusetts Institute of Technology; Harry Eagle, Albert Einstein College of Medicine; Herman Eisen, Washington University; Judah Folkman, Harvard; Paul Marks, Columbia University; Rufus Miles, Washington, D.C.; George Palade, Rockefeller University; Helen Ranney, State University of New York at Buffalo; Alvin Weinberg, Oak Ridge National Laboratories.

On the other hand, some of the members of the review committee worried that the systems analysis approach might "represent the underlying philosophy of the whole program." Carrese wants to know why that prospect should worry anyone.

The reviewers addressed themselves to the issue of centralization of planning of research and felt uncomfortable with their impression that there is going to be too much of it.

"It seems to us a defect of the NCPP [cancer plan] that the enormity of our ignorance about cancer receives less emphasis than it merits. Much is said about the lines of research that appear most promising today—virology, cellular immunology, and genetics, for example—but too little acknowledgment is made of the genuine possibility that any or all of today's leads, including all of those proposed by the 250 scientists in the Airlie House Conference, could turn out to be the wrong leads."

The plan fails, they said, because:

"It leaves the impression that all shots can be called from a central headquarters; that all, or nearly all, of the really important ideas are already in hand, and that given the right kind of administration and organization, the hard problems can be solved. It fails to allow for the surprises which must surely lie ahead if we are really going to gain an understanding of cancer."

They went so far as to propose that certain areas of basic research are, per se, relevant to cancer and should, therefore, be funded by the NCI whether the investigators doing the work consider themselves cancer researchers or not. Their choices: DNA replication, the cell cycle, regulation of transcription, regulation of membrane assembly and function, cell differentiation, regulation of protein synthesis, and all aspects of cellular immunity. They indicated they would be perfectly happy to see them changed as cancer progresses.

The institute review committee then tried to soften its criticism by saying these defects in the plan may be merely a matter of language, not one of intent on the part of the cancer planners. But they are not very convincing. Their concern with targeted research is pervasive and it is significant because, whether the planner intend centralization and rigidity or not, vast numbers of scientists—young and not so young—believe that this is the effect the plan will have. That in itself is stifling.

One of the primary sources of discontent among "cancer" scientists in both clinical and fundamental research is the feeling that they have surrendered control of the direction of science to the administrators of the NCI. The verbal protestations of those administrators notwithstanding, many members of the scientific community share the impression that the important decisions about what to fund and at what level are being made almost exclusively by content among "cancer" scientists in NCI officials whose interpretation of what is suitably part of the cancer program and what is not does not square with their own.

The authors of the Institute of Medicine's review based their concern about an excess of planning on their reading of the cancer plan. To some extent, their concerns were validated recently at a meeting of the advisory committee of the NCI's "molecular control" program, which could be one of the principal channels for funding basic research in the cancer crusade. Issues raised at that meeting are likely to come up again and again as the cancer program takes shape. The molecular control program, new to the NCI table of organization, is headed by Timothy O'Connor, a virologist by training, who is respected as one of the most scientifically sophisticated administrators in the institute. O'Connor, visibly enthusiatistic about his program, is particularly anxious that it foster interdisciplinary research. The advisory committee includes a couple other NCI staff members and several university scientists. Their job is to define the goals of the molecular control program, take a hand in implementing them, and to offer an opinion on whether specific contracts (or possibly grants) should be approved. Such recommendations then go to the NCI brass for final action.

From the outset, it was apparent that some of the university scientists did not fully understand how the NCI operates; nor did they fully agree with some of the premises of the NCI program once they got them straight.

When the meeting opened, O'Connor informed the group of four contracts that had won final clearance. The conversation quickly turned to policy when Christian B. Anfinsen, who shared the 1973 Nobel prize in chemistry, asked about how contracts originate. Do they just come from the "stratosphere" for approval, or can the committee initiate things, he queried.

O'Connor said that the ideas for contracts are often generated by investigators themselves at the annual NCI meeting for contractors. Saul Schepartz added to the answer, saying, "Every once in a while you might get a really good proposal that is unsolicited [by NCI], but then you have to ask whether it fits our program." Anfinsen found the answer "disappointing."

The meeting moved on. The committee set about defining the goals of the molecular control program and, after some discussion, agreed on four, roughly as follows: (i) membrane processes, including structure and membrane interactions with various agents; (ii) replication, integration, and transcription of genetic material; (iii) mechanisms by which messenger RNA is processed and by which it translates the information coded in DNA; and (iv) integration of biophysics into research on all of the above.

The goals won general acceptance as being broad enough to encompass a considerable variety of research, but they were not accepted without reservation. Anfinsen asked, somewhat rhetorically, "Our four goals essentially all say the same thing—control of protein synthesis [is important]. Might we be missing something?" The question passed, but other knotty questions arose as the discussion progressed to the ways of implementing research on the goals.

It seems safe to draw the conclusion that the non-NCI scientists present shared O'Connor's conviction that the program must be interdisciplinary. Britton Chance of the University of Pennsylvania pressed the cause of biophysics and had no trouble winning his colleagues to his view. William Joklik of Duke University was firm in his belief that the fields of protein synthesis and membrane biology and related areas could probably benefit from the help of some good organic chemists. He mentioned the problems that nucleic acid workers are having in getting an iodine tag on the RNA molecule without breaking it and postulated that an organic chemist might have the solution. That sounded sensible. (Years ago, it was an organic chemist who helped James Watson and Francis Crick work out the structure of DNA.) There was a suggestion that one thing to do would be to let the entire scientific community in on the idea of soliciting organic chemists by publishing, in some conspicuous place, the fact that the cancer program was open to the contributions that organic chemists might make.

That did not go over as well. One of the NCI administrators warned that the result of such a general announcement would merely be a flood of grant applications, many of them from "nuts," and that the NCI is swamped with applications as it is. Furthermore, there is the matter of limited funds. A proposal to organize small conferences to which a few investigators from fields not traditionally connected with cancer would be invited won greater acceptance from the NCI people. Some of the committee members just could not shake the feeling that NCI wants to call the shots, relying less on the advice of outside people than ever.

## RELEVANT RESEARCH ONLY

The other issue that pervaded the discussion was the matter of relevant versus irrelevant research. Is there such a thing as good membrane research that is relevant to the cancer program and good membrane research that is not? Such a question seemed to some to be marginally out of place at a meeting devoted almost entirely to very fundamental research problems, but the question was very much there nevertheless. O'Connor mentioned several times that the overriding aim of the molecular control program is to use appropriate research findings to develop new, rational approaches to the design of drugs for eventual use at the bedside. O'Connor expressed it simply: "Good science for its own sake, no matter how beautiful it is, will not get funded. Good research that may lead to cancer control will." (After the meeting, O'Connor reiterated his position. The idea is to translate—through deliberate effort—basic discoveries into something practical—namely, a drug. To this end, he hopes scientists can learn to see how their work can be used in ways they might not otherwise have considered. "The end of a good experiment has to be more than just the publication of a paper that sits on a shelf," he said.)

Again Anfinsen, who by his own admission was not happy with the framework he felt he'd been forced into, spoke up. "The nub is that we can tell good science that is relevant from good science that is not. I don't think I can."

In a sense, there are two issues here and, in one regard, less discord than appears on the surface. Certainly, one is the issue of relevant research and the extent to which anybody can be sure what that is. Underneath that is the issue of money and the ways the NCI as a whole chooses to allocate it. Anfinsen is talking about principles. O'Connor is trying to get the most sophisticated science he can for a comparatively meager amount of money. The molecular control program, which, no matter what its limitations, is considered by many cancer workers to be one of the more promising of the NCI programs, has an indefinite budget. So far, it has allocated about $1 million.

If one puts that beside the budget for the traditional NCI drug screening program—as both clinicians and basic researchers do—one raises a question that has come up before but which many people still think needs answering. Under the category of cancer treatment, the drug screening program has $23,900,000 or 46 percent of that category's total budget. Anfinsen, who was not buying much of anything the day of the molecular control program meeting, spoke to the issue with regard to a contract the molecular control program itself has given out.

The program, with the approval of its advisory board, has awarded Litton Industries a $301,000 contract to screen anticancer drugs and antiviral agents. Anfinsen suggested that, if the "silver bullet" approach to curing cancer is to be pursued under the heading of molecular control, it might be wise to award the same contract to two groups to see if competition would lead to a better idea. "Screening has been going on at NCI for a long time and not much has come of it," he said. "It is like trying to get to Mars by building a more powerful moon rocket. It's not very imaginative." O'Connor defends this drug screen as being different from the rest. It will only look at compounds carefully selected as potential anticancer drugs on the basis of their molecular structure. It will not be a random screen and will limit itself to about 800 compounds a year. (The existing screen-program, which uses an animal system to identify promising agents, tests almost 40,000 compounds a year.)

The advocates of the existing drug screening program can, of course, point to the present arsenal of anticancer drugs as vindication of their efforts—and they have a case. But the questions being raised address themselves to matters of proportion—priorities, if you will—and in this there is still no resolution. The NCI administrators have the upper hand, or, at least, the scientific community thinks they do. And it has no tangible evidence that it is misreading the situation. It may just be a matter of approach—the two "sides" may not really be hopelessly far apart—but it is hard to believe much significant progress will be made until these issues are set straight.

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[From the Medical World News, July 12, 1974]

## THE LINES OF CANCER RESEARCH

### IN THE WAR AGAINST CANCER, EXPERTS DO BATTLE OVER HOW MUCH TO SPEND ON "CURABLE" PATIENTS, HOW MUCH ON BASIC RESEARCH

Most people who get cancer die because of it. It is true, as previous articles in this series have indicated, that during the past ten years there has been some remarkable progress in treating—even curing—a few relatively uncommon forms of cancer. And it is apparent to constant observes of the "politics" of cancer that both the American Cancer Society and the National Cancer Institute are placing new emphasis on the positive things that can be said about this horrible killer. "In the 1930s fewer than one cancer victim in five was being saved," spokesmen for both groups frequently tell audiences. "Today, we're saving one in three."

That sounds like progress, and it is. Advances in surgery and radiation therapy, along with the advent of chemotherapy, have certainly given physicians new powers in their fight against cancer. And, to add further hope, there is immunotherapy, admittedly still in experimental stages but coming along fast. As Dr. Wiliam D. Terry, NCI's chief immunologist, says, "Immunotherapy today is in about the same stage of development that chemotherapy was in a decade ago."

But for all this, the fact remains that cancer is anything but a curable disease. The ACS' own figures tell the story. "Of every six persons who get cancer (exclusive of superficial skin cancer and carcinoma in situ of the uterine cervix) today, two will be saved and four will die. Numbers one and two will be saved. Number three will die but might have been saved had proper treatment been received in time. Numbers four, five, and six will die of cancers that cannot yet be controlled; only the results of research can save these patients."

These are the facts. Since December 1971, when President Nixon signed the National Cancer Act, as a "Christmas present to the nation," this country has been engaged in an expensive war on cancer, launched to do something to change the facts. The director of the NCI, Dr. Frank J. Rauscher Jr., is the commander of the cancer crusade.

The war on cancer is really two wars. One pits physicians and scientists against tumors; the other has cancer researchers fighting each other. The National Broadcasting Company aptly dubbed it the "war within the war," and it is being waged over money. Prior to December 1971, when the cancer institute was just an institute like any other within the National Institutes of Health and cancer research was conducted without the fanfare of a national campaign, the total NCI budget was $233 million (for fiscal 1971), a sizable sum even then. With the signing of the cancer act, however, came more money. In fiscal 1972, the NCI got an increase of $145 million, filling its coffers to a munificent $378 million. In 1973, Congress told the NCI it could spend $492 million. But the President's Office of Management and Budget said "nothing doing" and gave the NCI only $432 million. In 1974, there was more haggling, with the White House taking a conservative stand; but the NCI came up with a total of $589.2 million, in part because the courts ordered the release of money impounded the previous year, money added on now to 1974 budgets. (The President's original request for 1974 was $500 million.) The NCI will spend at least $600 million in fiscal 1975, and that is a lot of money to fight about.

How much money should be spent on cancer control that, among other things, is focused on saving the person the ACS calls patient number three, the one who might have been saved if only he had received the right care soon enough? How much should be spent on basic research, on helping patients four, five, and six who, as things stand now, are doomed no matter what anyone does? Theoretically, these should not be mutually exclusive goals; but practically, even with the comparatively vast resources of the cancer war, there does not seem to be enough money to go around.

Because of the progress that has been made in diagnosing and treating cancer, the NCI has arrived at new feelings about what now constitutes the "best available care" for cancer victims and is attempting to make it widely available through various means. Certainly, some dissemination of the latest therapeutic advances takes place through the Comprehensive Cancer Centers (CCC) program. (There will soon be some 18 CCCs throughout the country, and the NCI estimates that about half of the U.S. population will be within half a day's drive of one of them.) More formally, efforts to make sophisticated information widely available are made through the Cancer Control Program. It is through this program, for example, that physicians might learn about the NCI's conviction that a "team approach" to the cancer patient is best—one in which the skills of the surgeon, radiologist, and chemotherapist are brought to bear from the start. In fiscal 1974, this program will cost $34 million.

Dr. Rauscher calls the Cancer Control Program "the most important new component of the National Cancer Program. It is just not right to have some child die of leukemia just because he doesn't live in the right town. We have the know-how to save them—we're probably reaching only 50% now—and we've got to reach more."

No one is about to come out and flatly disagree with that, but there are individuals in the cancer community who believe that the emphasis on the here and now is unwarranted in light of the fact that funds for research are restricted. Some of these persons sit on the National Cancer Advisory Board, the Presidentially appointed body that oversees the conduct of the war on cancer. Generally, they prefer to stay out of a public debate on the issue although they speak out in private and, reportedly, in closed sessions of the board.

One of the more articulate spokesmen for the primacy of research is not a member of the board but is, nonetheless, influential in cancer circles. Dr. Lewis Thomas, president of Memorial Sloan-Kettering Cancer Center in New York, is a crusader against what he calls "halfway technology" and against the presumption that science knows enough about cancer to mount any kind of organized attack on it. Of halfway technology, he has written: "This represents the kinds of things that must be done after the fact, in efforts to compensate for the incapacitating effects of certain diseases whose course one is unable to do very much about. It is a technology designed to make up for diseases or to postpone death. . . . Much of what is done in the treatment of cancer, by surgery, irradiation, and chemotherapy, represents halfway technology, in the sense that these measures are directed at the existence of already established cancer cells, but not at the mechanism by which cells become neoplastic.

"It is a characteristic of this kind of technology that it costs an enormous amount of money and requires a continuing expansion of hospital facilities. There is no end to the need for new, highly trained people to run the enterprise. And there is really no way out of this, at the present state of knowledge."

Control programs in general have not fared well at the NIH, in the NCI or any of the other institutes in which they once existed. The idea seemed to be that the proper mission of the NIH is research, not the delivery of medical care in any general form, and so, control programs were discontinued. This disturbed members of the House of Representatives Committee on Interstate and Foreign Commerce considering enactment of the National Cancer Act during deliberations prior to its passage. "The committee was very disturbed to find in its study of the cancer problem that identifiable funding for cancer control programs cleared with fiscal year 1970 and that a number of the activities previously supported through these programs have in one way or another been terminated or allowed to lapse," a committee report stated.

Favoring some "public health" aspects of a cancer program while also stating that the NCI should not get into the business of practicing medicine, the committee declared: "The NCI should not be involved in extensive patient care activities to demonstrate the effectiveness of a particular technique or finding. Yet the committee sees an important role for NCI in bridging the gap between research and general medical application. Once the effectiveness of these findings can be demonstrated—to the satisfaction of the scientific community—these results or techniques should be expeditiously communicated to the medical practitioner."

The line between "demonstrating" and "delivering" care is thin, and which side of it the control program was going to end up on has been subject to differing interpretations from the start. It remains so now that the program is finally getting under way after a slow start. In spite of what may seem to be the clear intent of Congress, as expressed in the committee report, the law itself is less clear, and—at the beginning—Dr. Rauscher had problems in getting agreement on the extent of cancer control activities. He was supported by people on Capitol Hill, particularly Rep. Paul G. Rogers (D-Fla.), and by the ACS, a strong ally. In fiscal 1972, the Cancer Control Program did not have a nickel, but by 1973 it had been given special budgetary attention and got $7 million with which to get started. Says Dr. Rauscher: "Significantly, Congress and the Office of Management and Budget provided new funding for cancer control, which was not at the expense of funds for basic, fundamental research." Not everyone agrees with the latter part of that statement.

Among the problems cancer control has had in getting started was finding a director. The first one appointed did not work out well and was assigned to other duties within the NCI. At the eleventh hour, his replacement was unable to move to Washington for personal reasons. It was only a few months ago that Dr. Diane Fink, who has been with the NCI since 1971, was named director of cancer control. She says she has no illusions about the dimensions of the task she is taking on.

## THE WAR ON CANCER: THAT'S WHERE THE MONEY GOES

The simple fact that this country has legislatively declared war on cancer and that the White House more or less endorses this war has meant that the money available for cancer programs of various sorts has tripled since 1972. It is true that Congress is willing to give the cancer program more than the President will allow; to that extent, the war on cancer is not being funded as well as some people think it should be. Nevertheless, money for the cancer program is nearly double the amount earmarked for its nearest fiscal competitor, the National Heart and Lung Institute.

The National Cancer Institute will spend $600 million in fiscal 1975. All told, says NCI Director Rauscher, the cancer institute has been spending about 50 percent of its funds for grant-supported activities. With an increase of about $23 million from fiscal 1974, the NHLI will spend about $310 million. And for fiscal 1975, all of the other institutes combined received a total budget increase of approximately $1 million.

Discussing the program with MWN, Dr. Fink said that the basic function of cancer control is education—of the public and of the practicing physician. There are, she explains, three major intervention areas: cancer prevention; detection, diagnosis, and pretreatment evaluation; treatment, rehabilitation, and continuing care. Among the program's more extensive projects is one begun last year to disseminate information on effective therapy for three "curable" cancers—acute lymphocytic leukemia, Hodgkin's disease, and non-Hodgkin's lymphomas. Chemotherapy will play an important role in this demonstration program, which designates seven "primary" hospitals to act as the focus of regional networks involving 120 community or "contributing" hospitals. The seven primary hospitals, at which oncologists will demonstrate the "most effective methods of diagnosis and therapy for all three types of cancer," are: Childrens Hospital of Los Angeles; Children's Hospital Medical Center, Cincinnati; Dartmouth Medical School, Hanover, N.H.; University of Alabama Hospitals and Clinics, Birmingham; Children's Hospital, Denver; New York Hospital-Cornell Medical Center; and Mount Sinai School of Medicine, New York City. The first year's operation, during which the program was being organized, cost $2 million.

The control program is also preparing to demonstrate the effectiveness of the Pap smear in detecting cervical cancer in a screening program of 42,000 women (many members of minority groups) in the Southwest. That project will cost $80,000.

Concern for the effectiveness of various educational programs aimed at teaching the public and health professionals alike about the dangers of smoking is another item on the cancer control agenda. More than $1.5 million will be spent "evaluating" them.

Many basic scientists are unhappy to see money from the cancer program going into projects such as these, contending that it could be better spent on research that may shed light on the fundamental aspects of cancer which, they believe, will be necessary before any truly satisfactory clinical progress can be made.

The need for greater emphasis on fundamental research was spelled out by a committee of the Institute of Medicine-National Academy of Sciences, appointed to review the National Cancer Plan, the master plan for the war on cancer. "It seems to us a defect of the cancer plan that the enormity of our ignorance about cancer receives less emphasis than it merits. Much is said about the lines of research that appear most promising today—virology, cellular immunology, and genetics, for example—but too little acknowledgment is made of the genuine possibility that any or all of today's leads . . . could turn out to be the wrong leads."

The Institute of Medicine committee, headed by Dr. Thomas who was, at the time of the review, just moving to Sloan-Kettering from Yale, spoke for the research community in asking whether the cancer program might become too rigid and make too many presumptions about what is known. "It [the plan] . . . leaves the impression that . . . given the right kind of administration and organization, the hard problems can be solved. It fails to allow for the surprises which must surely lie ahead if we are really going to gain an understanding of cancer."

What might those surprises be? Which areas of basic research might reveal truths about cancer? The committee boldly made a stab at some suggestions: DNA replication, the cell cycle, regulation of transcription (the process by which DNA passes its genetic information on to RNA), regulation of membrane assembly and function, cell differentiation, regulation of protein synthesis, and all aspects of cellular immunity. The point the committee wished to make is that the NCI consider funding many kinds of basic work, whether they are clearly labeled cancer research or not.

Although there are dozens of ways to go about looking for basic information about cancer cells, there is a common denominator for them all. Scientists are looking for "differences." In what ways, they ask, are cancer cells different from normal cells. The one distinguishing feature of malignancy is, of course, well known. Cancer is characterized by—in fact defined as—uncontrolled growth. In circumstances in which normal cells show self-restraint, cancer cells show none, proliferating without regard for the normal tissue they are destroying in their wake. The question is why?

One area of basic research that has received growing attention during recent years is the study of the cell surface or membrane. It is clear that the surface properties of tumor cells differ from those of normal ones, both in the antigens they possess and in the structure of the membrane itself. There are many researchers in this field. Says Dr. Garth L. Nicolson of the Salk Institute in San Diego: "The cell surface is the critical structure by which cells recognize and communicate with one another. The surface is bounded by a very thin membrane, approximately one half millionth of an inch, that is made up of proteins, lipids, and sugar molecules."

To see what happens to membrane molecules when a normal cell is transformed to a cancerous state, Dr. Nicholson, and his colleagues grow them in tissue culture. In a Petri dish, normal cells will grow until a contained population of cells forms a monolayer, or single covering. Tumor cells pile up on top of one another. Using a lectin—a plant protein that binds to sugar molecules—as a probe, Dr. Nicolson discovered what may be an important difference between tumor and normal cells. When normal cells come into contact with one another, he has reported, they modify their surfaces by dramatically increasing concentrations of a particular sugar residue in their membranes. Tumor cells show no such surface modification, continuing to grow as though they had not recognized the presence of other cells in the environment. "Thus," says Dr. Nicolson, "the processes that regulate the growth of normal cells may, in part, be signaled in normal cells by this change in sugar polymers."

Nobel laureate Robert W. Holley, also of the Salk Institute, is another membrane investigator, although his version of how things work is somewhat different from Dr. Nicolson's. Dr. Holley has been looking at normal and malignant cells in culture and at temperature-sensitive mutants—cells that behave normally when incubated at high temperatures and that behave malignantly at low temperatures. What Dr. Holley finds is that cell behavior is related to concentrations of various nutrients in its environment—in this case, culture medium—and that a cell may be what it eats.

"Growth is regulated by a complex interaction of many factors," he concludes, rejecting the belief of many of his scientific colleagues that there are clear-cut "on-off" switches in cells. Instead, he believes that normal cells divide when their intracellular concentration of nutrients is adequate; in other words, when they have had enough to eat. This is all directly related to membranes because it is through the membrane that nutrients enter the cell. Dr. Holley postulates that certain "serum factors" that he is trying to characterize may affect the permeability of the membrane and, therefore, control the flow of nutrients to the cell. Theoretically, in cancer, changes in the membrane may be such that the cell is no longer under the influence of these regulatory serum factors. Nutrients enter without restriction. The cells divide continuously.

From a slightly different perspective, immunologists are also interested in cell membranes because it is there that antigens of various sorts reside. All cells, normal and malignant alike, have surface antigens. They are among the components or features of the cell that give it its unique identity. Those on tumor cells are unlike antigens on normal ones and label the tumor cells as "foreign" and, therefore, in ideal circumstances, susceptible to recognition and destruction by the immune system.

According to one theory, known as "immune surveillance," cells of the immune system are constantly surveying the body, on the lookout for foreign cancer cells. It may even be possible that the immune system evolved for the purpose of protecting against cancer, some investigators hypothesize.

The immune system is divided into two parts. One line of defense is built of B (bone marrow-derived) cells that make antibody. The other is composed of T (thymus-derived) cells of T lymphocytes that provide what is known as "cellular immunity." It is this part of the system, many investigators believe, that bears primary responsibility for coping with cancer.

During the past couple of years, there has been notable progress in studies of the immune system, which Dr. Robert W. Baldwin of the University of Nottingham, England, summarized at a recent meeting of the American Cancer Society. He said that it is known that both experimentally induced and spontaneous tumors in animals frequently "express" cancer antigens, and that the nature of these antigens seems to be related to the agent that induced the cancer in the first place. For example, cancers induced by chemicals have one type of antigen. Those caused by viruses have another. In the case of viruses, in fact, it has been shown that the antigens or immune properties of the virus and those of the tumor are related, indicating considerable specificity.

Human tumors, too, show specificity in the antigens they express. There are, for example, antigens thought to be characteristic of breast cancer. And there is evidence that many human tumor antigens are actually fetal antigens that, for some reason, are being re-expressed in adulthood. This observation, among others, has lead to the idea that cancer is really a problem of cellular maturation or differentiation. (Carcinoembryonic antigen and alphafetoprotein are in this category; they appear to have usefulness in tumor diagnosis and in monitoring the therapeutic course of patients with certain types of cancer.)

For reasons that are not yet understood, there are times when tumor cells elude the ability of the immune system to handle them. Paradoxically, one explanation, first put forth by Drs. Karl and Ingegerd Hellstrom of the University of Washington in Seattle, is that antibodies or some other factor in blood serum blocks the cancer antigens, masking them as it were.

Dr. Baldwin discusses an extension of that idea. "The view, now gathering acceptance, is that growing cancer cells release or 'shed' cancer distinctive antigens from the cell surface into the tissue surrounding the cancer growth and ultimately into the circulation. The released cancer substance will combine specifically with circulating cancer-specific antibodies also in the circulation so that there are a number of ways in which cancer-directed immunity can be inhibited." The picture becomes more and more complex as research continues.

Dr. Alexander R. Lawton of the University of Alabama in Birmingham looks at the immune system and cancer from the point of view of B-cell differentiation and the need to understand the ways in which cells "talk to each other." Differentiation, he notes, occurs as a consequence of gene expression. "It is possible to make the generalization that a critical factor in initial steps of differentiation for an uncommitted cell is supplied by other cells in its immediate environment. This concept of inductive differentiation microenvironments is particularly well illustrated in the development of the immune system."

With Drs. Max D. Cooper and Paul Kincade, Dr. Lawton has worked out a scheme to account for B-cell differentiation. The cell starts out life as an uncommitted stem cell, first found in the yolk sac of embryos, and then migrates through the bloodstream to the fetal liver. There, controlled by influences supplied by its environment, it becomes a B-cell, first recognizable as such by its ability to synthesize a particular immunoglobulin, IgM. Unlike plasma cells that also synthesize antibody (in large quantities), the B-cell makes only small amounts of IgM, which it tucks into its membrane. There, Dr. Lawton says, the B-cell-made antibody acts as the cell's trigger mechanism, reacting to antigens to which the cell is exposed. Under normal conditions, the B-cells presumably then direct the synthesis of antibodies suitable for the situation.

But there are certain B-cell malignancies in which it is apparent that the ability of the population of cells to differentiate properly is impaired. One of these is chronic lymphocytic leukemia in which the B-cells proliferate, slowly but continuously. Another is multiple myeloma. B-cells at a more mature stage of development than those in lymphocytic leukemia are, again, growing out of control. "The importance of control of differentiation in understanding malignancy has probably not received the attention it deserves," Dr. Lawton says, although he is hopeful that further studies of lymphocytes will contribute a solution to the problem.

In most cases, it is the ability of cancer cells to metastasize that is the most frustrating (and fatal) aspect of the disease. Immunologist Isaiah J. Fidler of the University of Pennsylvania School of Medicine believes that surface properties of the tumor cell determine whether it will or will not spread. He maintains that it is the tumor cell that manipulates the immune response, not the other way around, and that there may be two functionally different types of immune cells, "one of them stimulatory and the other inhibitory."

Dr. Fidler and his associates have been investigating the role of lymphocytes and macrophages in the phenomenon of tumor growth and spread. What they suggest is that lymphocytes may play a dual role, sometimes stimulating and sometimes inhibiting tumor growth but that macrophages, once recruited into action by sensitized lymphocytes, are uniformly anticancer agents. He believes that if macrophages could be suitably sensitized, they could come to play a major role in cancer therapy.

Molecular biology and immunology are gaining new recognition for their role in the study of cancer. Virology, one of the fields that had dominated cancer research during the past decade, continues to flourish, although its directions are changing. During the past few years, the search for a human cancer virus has been intense and highly competitive. Scientists hoped that if only they could get their hands on the human cancer virus—or viruses—they all believed to be present in tumors, they could design a simple and effective way to eliminate cancer. It has not proved to be nearly that simple.

Those human cancer viruses that have been reported, always with much fanfare, have turned out to be animal viruses after all. And now, as virologists probe tumor cells with new sophistication, they are becomnig more concerned with finding "footprints" of viruses, or pieces of virus, than they used to be with getting the whole virus itself. Dr. Sol Spiegelman, director of the Institute for Cancer Research at Columbia University, put things in perspective somewhat glibly recently with this prediction: "I predict that one or two cancer laboratories in the U.S. will succeed in isolating a human cancer virus this year or, if they don't, big deal."

One of the principal cancer virus theories promulgated recently is the oncogene hypothesis put forward in 1969 by Drs. Robert J. Huebner and George J. Todaro of the NCI. Simply put, they propose that every cell in the body contains the genetic information necessary for the production of C-type RNA viruses, known to cause cancer in animals, and that it is this "oncogene" that causes cancer in man when it is turned on or "depressed" by some event.

Dr. Spiegelman claims he has data that show that the oncogene hypothesis is not true, especially because it says that the genetic information for cancer is present in every single cell from the beginning of life. In the past few months, he has studied twins, one of whom had leukemia and one of whom did not. By using a technique called molecular hybridization (which he pioneered), he has shown that there is genetic information in the cells of the leukemic twin that suggests the presence of a tumor virus—but no such information in the cells of the healthy twin.

Dr. Robert C. Gallo and his colleagues at the NCI also suggest that the oncogene theory may be incorrect and in need of some modification. Dr. Gallo, who has been looking at the role of RNA viruses in animal and human cancer, says: "The weight of evidence appears to be moving away from the concept that 'oncogenes' exist in cells in a dormant state and toward the idea that oncogenic sequences [of viral genetic information] are acquired by genetic modification of cell genes that then become associated with other viral genes."

Both Drs. Spiegelman and Gallo are among those whose studies make use of information that can be obtained by looking for reverse transcriptase in cells. First discovered in 1971 by Dr. Howard M. Temin of the McArdle Laboratory for Cancer Research at the University of Wisconsin and Dr. David Baltimore of the Massachusetts Institute of Technology, reverse transcriptase has played an important role in cancer virology. It is an enzyme that allows an RNA virus to make DNA, reversing the usual DNA-to-RNA process of genetic transcription and has given researchers new ways of probing cells for viral information.

Dr. Gallo and Dr. David Gillespie, also of the NCI, have just suggested a new theory about cancer and viruses. They call it RNA processing. They support the notion that the normal function of RNA viruses is not to cause cancer, but to aid in the process of differentiation and development. Cancer arises when there is an error in their expression, when the process of converting the genetic information they contain goes awry.

"The possible relation between RNA processing and the production of RNA tumor virus genomes is important not only from the point of view of understanding how frank animal tumor viruses originate and are maintained in cells, but it is also useful as a basis for evaluating human cancer," say Drs. Gallo and Gillespie. "If an unusual mode of RNA processing can be generally documented in human tumor cells and the responsible event elucidated, then a single mode of therapy aimed at this event may be useful in the treatment of neoplastic diseases."

For the busy clinician facing his cancer-stricken patient today these lines of fundamental research hold out at best a hope for men and women he may never see in his lifetime. But his interest can never be put into neat categories labeled "academic" and "practical." When the war on cancer is finally won, the observations of informed physicians will play a vital part in the victory, as they do in bringing the best available care medicine can provide to cancer victims now.

Senator KENNEDY. The subcommittee stands in recess, subject to the call of the Chair.

[Whereupon, at 2:20 p.m., the subcommittee recessed, subject to the call of the Chair.]

**Calendar No. 710**

93D CONGRESS } SENATE { REPORT
*2d Session* } { No. 93–736

# NATIONAL CANCER ACT AMENDMENTS OF 1974

MARCH 20, 1974.—Ordered to be printed

MR. KENNEDY, from the Committee on Labor and Public Welfare, submitted the following

# REPORT

[To accompany S. 2893]

The Committee on Labor and Public Welfare, to which was referred the bill (S. 2893) to amend the Public Health Service Act to improve the national cancer program and to authorize appropriations for such program for the next 3 fiscal years, having considered the same, reports favorably thereon with an amendment (in the nature of a substitute), and recommends that the bill as amended do pass.

## I. Accomplishments of the National Cancer Program

The Committee feels that since its inception a little more than two years ago, the National Cancer Program has made substantial progress. To some observers, research progress has seemed too slow, yielding few significant reductions in the overall impact of the disease. But, dramatic progress has been achieved against several types of cancer and hopefully other cancers may soon yield to new and exciting research approaches now underway. The difficulty of the cancer problem is illustrated by the fact that in spite of the progress that has been made, one of every four of our citizens will develop cancer in their lifetime. According to the present trends, 665,000 new cases and nearly 350,000 deaths from cancer are expected in 1974.

There has been little improvement in life expectancy, for example, for patients with cancers of the pancreas or lung. For patients with pancreatic cancer, survival rates have shown no improvement in the past 20 years, while incidence of the disease has risen sharply. It is now the fifth most common cause of death from cancer in the United States.

Lung cancer kills more Americans than any other type of cancer—an estimated 72,000 persons will die of the disease this year—and its incidence has more than doubled since 1947 in both men and women.

One of the most frustrating aspects of lung cancer is that cigarette consumption continues unabated despite knowledge that the toll from this disease would be sharply reduced in future years by a comparable reduction in cigarette smoking now.

Yet there have been heartening advances. Forty years ago only one out of every five cancer patients could be expected to be free of all evidence of cancer five years after treatment. By 1970 that figure was one out of three. Improvements in life expectancy for patients with acute lymphocytic leukemia and Hodgkin's disease following aggressive treatment are well documented. This past fall the National Cancer Institute reported improvements in the percentage of patients surviving three years or longer following diagnosis of cancers of the urinary bladder, brain, larynx, prostate and thyroid, as well as among patients with chronic lymphocytic leukemia, multiple myeloma or melanoma of the skin.

The National Cancer Program is gaining ground against many forms of the disease and this effort will help ensure maximum sustained progress against all forms of cancer. While strengthening the ability of NCI to mount a broader, more intensive research attack, the Act also charges the National Cancer Institute with developing and coordinating a national strategy against cancer. Furthermore, the agency is given new responsibility for ensuring that research results are quickly and systematically put into widespread use for cancer prevention, detection, diagnosis and treatment.

The development and coordination of the National Cancer Program involves, first, the development of a consensus among clinicians and laboratory scientists about the direction, content and pace of the research program. The overall program strategy involves the systematic sharing of cancer information by public and private agencies throughout this country and abroad. It requires continued assessment of resources needs and logistical planning to meet those needs. In some cases, it necessitates the redeployment of existing facilities, the rapid evolution of new kinds and combinations of research support, the reassignment of science management responsibilities, and the development of new mechanisms of technological transfer and information retrieval and application.

### *Cancer Biology*

In studies of cells in tissue culture, work is in progress to identify changes in cell metabolism that accompany malignant transformation. A number of abnormal properties of transformed cells, for example, seem to be related to their inability to accumulate a chemical compound, cyclic adenosine monophosphate, that facilitates normal processes within cells.

Research in cancer immunology has been expanded, based partly on clinical observations that patients with defects in immunity have a high incidence of cancer. Cancer cells are, in a sense, foreign to the body. And the immune system seems to recognize them and to react to them. Although the reaction usually is not sufficiently strong to destroy the tumor completely, there are ways to stimulate the immune system so that it is more effective. Studies of this system have important implications to detection and diagnosis as well as treatment of cancer, and attention has been given this past year to planning a greatly expanded, coordinated national program of immunologic research.

Other factors are also involved in malignant transformation. For example, a chemical, isolated from some cancers, induces rapid growth of blood capillaries supplying the malignant tumor. It is thought that this capillary-inducing tumor factor must be present before the tumor can grow larger than a few millimeters in size. With further study and understanding, this factor, too, may eventually be exploited for cancer prevention and treatment.

*Cause and Prevention*

The Third National Cancer Survey, still being analyzed, provides incidence and prevalence data for the years 1969 through 1971 for seven metropolitan areas, two entire states, and the Commonwealth of Puerto Rico. Making the necessary statistical adjustments and excluding common skin cancers, the Survey findings indicate that approximately 610,000 new cancers were diagnosed in this country in 1969. This figure represents an incidence of 318 new cases of cancer for each 100,000 people in the U.S. population. The incidence for blacks (338) is substantially higher than for whites (311). The difference is particularly large between black males (371) and white males (335).

A number of trends are worth noting, based on comparisons with a 1947–48 survey of ten cities:

> The incidence among males increased almost 9 percent, while the incidence among females decreased 13 percent. The contrasting trend between the sexes was particularly marked among blacks.
>
> The increase among males is due largely to a substantial increase in the incidence of cancers of the lung and prostate, and a lesser increase in the incidence of colon cancer. The combination of these increases more than counterbalances the drop in the incidence of gastric and rectal cancers.
>
> The overall decrease among females reflects drops in the incidence of cancers of the uterine cervix (invasive), stomach and rectum. The only site with an important rise in incidence among women is the lung—the rate doubled from 6 to 12 per 100,000.

Previously, excesses of cancer incidence have been associated with occupation-related hazards of steelworkers, smelter refinery workers, asbestos workers, uranium miners, and others. In view of the importance of such exposures as a source of cancer, the national program has become more heavily involved in occupational epidemiology, in cooperation with the National Institute for Occupational Safety and Health, the Environmental Protection Agency, and other Government agencies.

Discovery of relationships between exposure to environmental chemicals and the development of cancer in man has usually been the first step toward knowledge about specific cancer causes. This provides the rationale for an extensive research effort to identify cancer-causing, or carcinogenic, chemicals in our environment.

Because almost all materials that have been demonstrated to be carcinogenic in man have also been found to be carcinogenic in animals—and because there is no ethical, sure way to test for carcinogenicity in humans—tests for carcinogenic hazards in animals have been developed and are being continuously improved. Approximately 1,000 chemicals have been found to cause cancer in animals, out of about 6,000 that have been tested.

Viruses are probably responsible for at least some human cancers. They cause many animal cancers. The possibility of finding viruses or any of the tell-tale viral proteins in human cancers has increased enormously with the development of (1) new immunological and biochemical methods of detection, (2) specific ways to activate viruses in tissues, and (3) other techniques to detect viral activities at the molecular level. One viral protein of particular importance is an enzyme called reverse transcriptase. This enzyme is found in tumor viruses of the ribonucleic acid (RNA) type and is thought to be a necessary element in the ability of these viruses to convert infected cells from normal to malignant. Once a virus is identified and its role in causing one or more types of cancer in humans is established, it may be possible to develop means to neutralize its activity. For example, it may be possible to develop chemical compounds to inhibit or block enzymes or other molecular activity of the virus in cancer cells, thereby killing the cancer cells or reverting them to normal. Identification of such viruses also could lead to ways to detect some cancers and to measure the success or failure of treatment in humans.

### *Detection and Diagnosis*

At the present time, most physicians believe that early diagnosis of cancer offers the best means to reduce mortality among cancer patients. Small cancers that have not yet spread can be removed surgically with an excellent probability of cure. Even if the surgeon cannot remove all the tumor, the earlier the disease is diagnosed, the better are the results and radiation and drug treatments. This is likely to be true for some years to come, despite the increasingly productive research effort on therapy with drugs and other modalities of treatment. Further, evaluation and application of the many exciting research results in chemical and viral carcinogenesis will require still longer to reduce cancer incidence.

The science of immunology has developed rapidly in recent years. An important application of research results in this field lies in the early diagnosis of cancer. In recognition of this applicability, National Cancer Program research in immunodiagnosis has been expanded.

An increasingly important part of this program is the effort to identify cancer antigens, chemical substances associated with malignant cells and thus candidates for the development of specific immunodiagnostic tests. One such test is for the carcinoembryonic antigen (CEA) often associated with bowel cancer. Although the CEA antigen does not, as originally hoped, specifically diagnose this disease, it is very useful as a "marker" to follow the progress of patients under treatment for various cancers.

Cytologic examination, the study of the characteristics of individual cells, has been used for some 30 years in a procedure known as the Pap smear for the diagnosis of cervical cancer and precancerous conditions. This kind of examination is now being used also for cells in sputum to diagnose lung cancer.

The Pap smear is the most important means for decreasing mortality from cervical cancer in this country, which could be reduced further by regular testing of all women. However, the number of tests that would be done would overwhelm the technicians available to do them. Automated analysis has been attempted in many laboratories and although systems being developed are not perfect, use of lasers and other new technology may reduce the number of specimens that technicians must examine, by identifying all of the clearly normal specimens.

Radiologic techniques are very important in the diagnostic localization of cancers in individual patients. Cancer of the breast can be screened by X-rays, using a conventional film technique known as mammography or the newer technique of xeroradiography. Thermography or the newere technique of xeroradiography. Thermography and ultrasound are two other techniques under study in the diagnosis of breast cancer—attempting to detect the presence of tumors by abnormalities in surface temperatures or transmission of sound, respectively.

A major advance in the clinical diagnosis of cancer has come from Japan in the development of fiberoptic examining instruments for detection of tumors by direct observation deep within body passages. These instruments employ bundles of tiny glass fibers which can be bent without distorting the image, or "picture" they convey. The devices include a fiberoptic colonoscope for visualization of the large intestine and a fiberoptic bronchoscope for probing all the major areas of the lung.

### *Treatment*

The long-term objective of cancer treatment is to cure or control cancer in man. Immediate goals are to increase the number of patients responding to therapy and to prolong the period of disease-free remission and survival.

Surgery, radiation and chemotherapy, either singly or in combination, have all been shown to be effective against particular cancers. In many instances, cure is achieved through removal or destruction of localized cancer, before it has spread to other parts of the body. Surgery and radiotherapy are the two major therapeutic approaches for the eradication of localized disease. Surgery is sometimes more successful when both the tumor and the nearby involved lymph nodes are removed. Radiotherapy is used to treat cancers that cannot be removed surgically. If metastasis has occurred, chemotherapy presently offers the greatest hope.

In general, various combinations of drugs or various combinations of treatment methods have yielded better results than single-drug or single-modality cancer treatment. On this basis, further studies seek to exploit the practicality of both combination chemotherapy and combination modality therapy.

A wide variety of single drugs with different mechanisms of action have been shown capable of inducing complete remission of acute lymphocytic leukemia for varying periods in anywhere from 7 to 50 percent of the children treated, depending upon the drug used. The same agents used in various combinations have been able to induce complete remission in 76 to 97 percent of the patients, a result clearly superior to the best of single agents.

During the last decade, not only has the number of useful leukemia drugs doubled, but clinical investigators have markedly improved their ability to control often fatal complications of the disease. Transfusions of white blood cells have been successful in combating some infections, for example, and transfusions of blood platelets are effective in controlling hemorrhage. In a few studies, relatively germ-free hospital rooms achieved through laminar air filtration systems are also significantly reducing the number of serious infections among leukemia patients. Using the best comprehensive treatment, five-year survivals have been achieved in some studies in up to 50 percent of patients with childhood leukemia.

Similarly, the prognosis of patients with Hodgkin's disease has steadily improved. Of those treated with a combination of four drugs (MOPP), between 60 and 70 percent of the patients are alive more than five years after the beginning of treatment, and more than a third of them have remained continuously free of the disease. By contrast, only 10 to 20 percent of patients treated with a single agent achieve complete remission, which usually lasts for only 10 to 30 weeks.

In breast cancer, there are six single drugs that produce a significant decrease in tumor size in 20 to 30 percent of the treated patients with advanced disease. This response is about the same as that observed with hormonal agents in cases of breast cancer without regard to stage of the disease. Combination regimens using the same six drugs can achieve significant temporary decreases in tumor size in approximately 60 percent of patients. These are not cures, but integration of combination chemotherapy with earlier treatment modalities of surgery and radiotherapy clearly offers the best hope for increasing survival rates in breast cancer and other solid tumors.

The ability of surgery and radiotherapy to increase cure rates of solid tumors is limited if small, often microscopic, traces of disease are already present at distant sites at the time of initial therapy. In such cases neither surgery nor radiotherapy of the primary tumor reaches these remote traces of disease, which can grow and ultimately result in death of the patient. Efforts to increase cure rates for solid tumors therefore are increasingly using drugs with surgery and radiation in primary treatment. In developing such regimens, new drugs and combinations are first tested against far-advanced disease. Those showing positive results are then evaluated for primary treatment of local and regional disease.

The Lung Cancer Working Group is presently developing and implementing a protocol whereby patients with high risk of recurrence are being treated utilizing various combinations of treatment methods following initial surgery, including radiotherapy and combination of drugs.

In the NCI Division of Cancer Treatment, the Brain Tumor Study Group has been established to evaluate the treatment of malignant brain tumors. Initial results indicate that the drug BCNU, a potent nitrosurea, is of value in the treatment of malignant glioma, a common type of brain tumor. A more detailed study just being concluded has evaluated the use of BCNU and X-ray therapy separately and in combination following initial surgery, and has compared findings with those from a similar group of patients receiving best conventional treatment of surgery alone. Preliminary results indicate combination therapies are superior.

The most promising new studies involving bone tumors have concerned Ewing's sarcoma, a usually fatal form of bone cancer occurring in children and young adults. A seven-year collaborative investigation indicates that intensive irradiation of the primary bone tumor can be combined with drug therapy to prevent the spread of cancer to other areas of the body. An increasing number of patients treated in this way are now living without recurrence of disease.

In addition to Ewing's sarcoma of the bone, other cancers which occur in children—Wilms' tumor, neuroblastoma, and retinoblastoma—are often cured with adequate radiation therapy given together with chemotherapy, or surgery and chemotherapy. Results of irradiation combined with chemotherapy have been encouraging in the treatment of patients with metastatic Wilms' tumor, a type of childhood cancer of the kidney. Drug treatment given before and after radiotherapy has helped arrest retinoblastoma, a cancer of the eye, and preserved useful vision in children whose prospects for sight were otherwise unfavorable. Neuroblastoma, a cancer of the sympathetic nerve tissue that usually occurs among children, is radiosensitive and often can be eradicated by combining irradiation with chemotherapy.

An emerging mode of treating cancer is immunotherapy. In this approach, stimulation of the immune mechanism provides the body with assistance in rejecting the tumor. For example, preliminary research with a tuberculosis vaccine, known as BCG (bacillus Calmette-Guerin), suggests its potential usefulness in the treatment of some cases of acute leukemia of childhood and of a malignant condition called melanoma. Results have been reported in only a small number of patients, however, and thus far are equivocal. Further studies are in progress to establish the effectiveness of this approach.

### *Rehabilitation*

Prior to the National Cancer Act of 1971, no national program existed for rehabilitation of the cancer patient. Some State and voluntary agencies do provide excellent rehabilitation services to limited numbers of cancer patients. However, only a few institutions in the country are capable of providing a full range of rehabilitation services to cancer patients.

During the past year, a comprehensive planning effort was initiated to develop a national rehabilitation program specifically for cancer patients. More than 100 rehabilitation experts, social service professionals and former cancer patients cooperated with NCI in defining specific rehabilitation research and demonstration projects.

Research and demonstration efforts will be directed toward changing pessimistic and fatalistic attitudes on the part of the medical profession and the public toward the cancer patient. Rehabilitation facilities, techniques, and educational programs for rehabilitation professionals will be developed. And projects will be supported to provide rehabilitation services to cancer patients in remote areas of the country, as well as in major cancer centers.

### *Delivering Research Accomplishments to the People*

Parallel in importance to research is the task of placing all usable information and skills in the hands of medical practitioners. The National Cancer Act of 1971 underscored this effort in providing for additional ways of expanding and expediting the translation of research results into effective clinical practice. Specifically, the Act authorizes the development of new comprehensive research and demonstration centers and the expansion of a specially identified cancer control program.

### *Cancer Centers Program*

The present centers program, which began in 1961, supports a broad range of specialized preclinical and clinical research activities in 47 institutions. Because the 1971 Act provides for 15 new clinical research and demonstration centers, the National Cancer Institute, in conjunction with the National Cancer Advisory Board, defined two major categories of cancer centers: comprehensive national research and demonstration centers, also called Comprehensive Cancer Centers, and specialized cancer centers.

By means of community outreach activities, Comprehensive Cancer Centers will provide coordination and leadership within their geographic regions to assure the availability of complete care for inpatients and outpatients with cancer. They will be responsible for coordinating multiple sources of support for educational, clinical, and research activities to produce a broad attack upon the complex problems of detection, diagnosis and treatment. Through a constant flow of scientific information, progress made in these Centers will benefit cancer patients throughout the country.

### *Cancer Control Program*

To close the gap between cancer research and the practical application of research findings, in and out of centers, the National Cancer Act of 1971 authorizes a Cancer Control Program. This new program encompasses projects of cancer prevention, detection and diagnosis, and treatment and rehabilitation. Most activities will be aimed at controlling the occurrence and impact of the ten leading causes of cancer deaths in this country: cancers of the lung, colon, breast, pancreas, prostate, stomach, ovary and rectum, plus the leukemias and lymphomas. Toward these ends, provisions will be made for the education of health professionals and the public, demonstrations to the public and medical community, the development of model systems for the treatment and management of cancer patients, and research seeking more effective means to utilize present knowledge about cancer.

The new Act provides discrete program recognition, separate funding, and specific, expanded responsibilities and authorities for these activities. The Cancer Control Program was established in 1972 within the Office of the Director of the National Cancer Institute, and began operations with the guidance of appropriate advisory committees composed of professional experts and public leaders.

The Cancer Control Program has begun to define other projects that can be started rapidly and have an impact in bringing proven research findings directly to the benefit of cancer patients. These include demonstration projects in rehabilitation; telephone consultations linking physicians in practice with cancer specialists; and the coordination of a geographic area's medical facilites to provde comprehensive cancer detection services for the population. Parallel efforts are being launched to identify and establish cooperative linkages with cancer control activities operated by other agencies—Federal, State and local—and by voluntary and professional groups.

*Cooperative Programs*

During the years since the passage of P.L. 92–218, an unparalleled level of activity tied together the work and mission of the National Cancer Institute with those of numerous Federal, State and local governmental agencies and with many private voluntary and professional organizations. In addition, again following the mandate of the National Cancer Act of 1971, NCI has expanded its cooperative efforts in the international sphere.

*NIH*

As a part of the largest biomedical research and development agency of the Federal Government, the National Cancer Institute continues to cooperate with the other elements that comprise the National Institutes of Health. There is a sharing of scientific knowledge as well as common concerns.

Activities in other institutes that provide the basis for close relationships and common interests among NCI scientists and their colleagues include:

Brain tumor research at the National Institute of Neurological Diseases and Stroke

Research on hormonal relationships to cancer at the National Institute of Child Health and Human Development

Cancer-related viral and immunologic studies at the National Institute of Allergy and Infectious Diseases

Oral cancer studies at the National Institute of Dental Research

In addition, cancer research has been furthered by the broad programs of the National Institute of General Medical Sciences and the other Institutes in support of research in the basic biomedical sciences. The multitude of approaches to the control of cancer have benefited and will continue to benefit from fundamental studies in many fields of science.

*Interagency Activities*

As indicated in foregoing sections of this report, substantial progress has already been made in coordinating cancer research and control activities conducted by Federal agencies as well as those of voluntary organizations.

Other specific arrangements made since the passage of Public Law 92–218 include a collaborative program for information exchange and cooperation in research areas focusing on environmental chemicals that cause cancer. In addition to NCI, the agencies involved are the Food and Drug Administration, the Environmental Protection Agency, the National Institute of Environmental Health Sciences, the National Institute of Occupational Safety and Health, and the National Center for Toxicological Research. Also, the Atomic Energy Commission, the Department of the Army, the Occupational Safety and Health Administration of the Department of Labor, the Department of Agriculture, and others.

Cooperation in a variety of other activities is also in effect with the Veterans Administration, Health Services and Mental Health Administration, and the Office of Naval Research. NCI, for example, provided funds to the U.S. Naval Research Laboratory in Washington, D.C., to make appropriate modifications of a cyclotron and associated facilities for preclinical research with fast neutrons.

### *State and Local Agencies*

NCI has utilized much of the material and data that have been provided through cancer registry programs of several states. This information has provided valuable assistance in epidemiological studies conducted through the NCI, including the Third National Cancer Survey.

Cooperative activities with State and local health agencies, for screening and diagnosis, are now ongoing. The educational role that these agencies play in informing the public of the necessity of early detection of cancer symptoms is vital to the mission of the Cancer Control Program.

### *Voluntary Groups*

There are a number of important private organizations, such as the American Cancer Society, the Leukemia Society of America, the Damon Runyon Cancer Foundation, the Candlelighters, and a large number of local and regional groups, each of which supplements and complements Federal cancer programs in effective and important ways. Through these organizations millions of Americans raise funds and do voluntary service in support of cancer research, professional and public education about cancer, and patient services.

The American Cancer Society is a unique organization because of its size, and because it so successfully bridges the lay and professional communities to conduct extensive and comprehensive programs ranging from public education about cancer, to support of scientific research. Its programs reach into cities and towns across America, thereby adding a dynamic and crucial dimension to the National Cancer Program. Although NCI has collaborated with the American Cancer Society and other voluntary organizations for many years, the National Cancer Act of 1971 calls for a new level of coordinated endeavors. Toward this end, NCI and the American Cancer Society have planned and are cofunding a network of projects for breast cancer detection as part of the NCI's Cancer Control Program.

### *International Activities*

International activities of the National Cancer Institute have been specially highlighted since the passage of P.L. 92–218 by an important new program of cooperation between the United States and the Soviet Union. As a result of the President's summit meeting in Moscow early in 1972, a U.S.–U.S.S.R. health agreement was signed. This agreement called for sharing results from cancer, heart disease and environmental studies. The Institute has followed through on this initiative, and specific joint activities are under way in chemotherapy, virology, immunology and genetics of tumor cells. These include:

Exchange of specialists, including short-term visits of senior scientific investigators of corresponding institutes for the development of concrete plans for cooperative research and for familiarization with results of ongoing research; and long-term visits by young specialists for detailed study of particular problems.

Exchange of antitumor agents for preclinical and clinical study and materials such as viruses, reagents, and biological specimens for basic research.

Joint meetings for discussion of specific questions of the chemotherapy and viral origins of diverse types of cancer.

Joint publications on cancer virus research and chemotherapy.

Exchange of information on chemotherapy and virology.

The International Union Against Cancer, with headquarters in Geneva, Switzerland, and the International Agency for Research on Cancer (IARC), with new facilities in Lyon, France, are receiving financial support from NCI. So, too, is the European Organization for Research on Treatment of Cancer. During the past year, for example, in collaboration with the Union and the World Health Organization, NCI sponsored a conference on childhood cancers. Major recommendations from that conference will be implemented by some 80 countries throughout the world and are expected to have considerable impact on the course of childhood cancer research.

## II. Need for Legislation—Hearings

The National Cancer Act of 1971 expires June 30, 1974. On January 24, 1974, Senators Kennedy and Javits introduced S. 2893, the National Cancer Act of 1974, designed to extend and improve the expiring authority for an additional three years.

Hearings were conducted by the Senate Health Subcommittee on January 30, 1974, on S. 2893. Testimony in support of the legislation was received from the following witnesses:

1. The Administration.
2. The President's Cancer Panel.
3. The Candlelighters.
4. A panel of cancer center directors including:
   Dr. Emil Frei III, Director, Children's Cancer Research Foundation, Boston, Massachusetts.
   John Durant, M.D., Director, Comprehensive Cancer Center, University of Alabama, Birmingham, Alabama.
   Dr. Jesse L. Steinfeld, Chairman, Department of Oncology, Mayo Clinic, Rochester, Minnesota.
5. The Association of American Medical Colleges.
6. American Cancer Society.

## III. Description of the Committee's Bill

The provisions of S. 2893, as introduced, included the recommendations of the National Cancer Advisory Board and the President's Cancer Panel.

Basically, the National Cancer Advisory Board and the President's Cancer Panel recommended that the program be extended for an additional three years with increased funding levels (See section V); that the current limitation in the Act for 15 comprehensive cancer centers throughout the nation be removed; that the Act be clarified to assure its continuation of Federal support for the training of cancer researchers of the future; that the authority in the Act respecting construction assistance be clarified so as to explicitly permit the construction of basic research facilities; that the authority of the Director of the National Cancer Institute to employ expert consultants be increased from 50 to 100 such experts; and that the authority of the Director of the National Cancer Institute be streamlined in order to permit the awarding of grants which do not exceed $35,000 in direct costs.

In executive session the Committee further amended the bill by including a number of provisions which were suggested by one or more of the witnesses who testified January 30, 1974. The Committee amendments are as follows:

1. The Committee has extended the authority of the National Institutes of Health to let research contracts which expires June 30, 1974. The Committee has permanently extended this authority.
2. The Committee has amended section 407(b) of the Act by including where appropriate data respecting nutritional programs for persons under treatment for cancer.
3. In order to assure an adequate number of competent personnel to administer the national cancer program, the Committee has amended section 407(b) of the Act by including the number and types of personnel necessary to carry out the program in the submission of the annual budget estimate for the program to the President.
4. The Committee has also amended section 410A(a) to assure that contracts be subjected to the peer review process.
5. The Committee has amended section 407(b) by including authority which requires the Director of the National Cancer Institute to conduct and contract for programs to disseminate and interpret information respecting cancer.
6. The Committee has amended section 454 of the Act to require the Senate to advise and consent in respect to the appointment of future directors of the National Institutes of Health.
7. The Committee has included an amendment which would permanently extend the expiring section 601 of Publc Law 91–296 respecting the availability of appropriations for the Public Health Service Act and the Mental Retardation Facilities and Community Mental Health Centers Act of 1963.
8. Finally, the Committee has amended Title IV of the Public Health Service Act by establishing new authority which proposes to establish the President's Biomedical Research Panel to be composed of the chairman of the President's Cancer Panel and 4 members appointed by the President who are exceptionally qualified to appraise the biomedical research program of the National Institutes of Health (including the research program of the National Institute of Mental Health). It further requires that at least three members of the President's Biomedical Research Panel shall be distinguished scientists or physicians. The panel shall monitor the development and execution of the biomedical research programs of NIH and shall report directly to the President. Any delays or blockages in the rapid execution of the NIH research program shall immediately be brought to the attention of the President and the Congress. At the request of the President, the panel shall submit for his consideration a list of names of persons for consideration for appointment as Director of the National Institutes of Health.

## IV. Committee Views

### A. *President's Biomedical Research Panel*

The Committee is alarmed that the integrity and vitality of this Nation's biomedical research program conducted largely by the National Institutes of Health is now threatened. The Committee believes that the Administration's budgets of the last several years, now seriously call into question this Nation's leadership in the quest for new knowledge upon which the medical sciences are based.

In enacting the National Cancer Act of 1971 the Committee intended to maximize the benefits of additional research opportunities respecting cancer. The Committee did not intend that increases for cancer research be funded at the expense of equally meritorious other biomedical research. Regrettably though, this Administration has chosen to consistently pursue such an ill-advised and short-sighted policy.

Based upon testimony which the Committee received at its hearings on S. 2893, and based upon subsequent communications the Committee has received (see No. IX—Appendix), the Committee believes decisive action is necessary to legislatively remedy this situation.

Accordingly, on February 19, 1974, Senator Kennedy, along with Senators Beall, Javits, and Schweicker, introduced S. 3023, a bill to to establish a President's Biomedical Research Panel to oversee and monitor the biomedical research program of the National Institutes of Health (including the research programs of the National Institute of Mental Health). This panel is directly modelled after the existing President's Cancer Panel and includes the chairman of the President's Cancer Panel as one of its 5 members.

The Committee believes that the President's Biomedical Research Panel will be as effective as the President's Cancer Panel has been under the remarkable leadership of its Chairman, Mr. Benno C. Schmidt.

In testimony before the Committee, the Association of American Medical Colleges indicated:

> The Association expressed its concern about the possible adverse impact that the singling out of one institute for special status and authority would have upon the other institutes and divisions at the National Institutes of Health. During the past few years, budget requests of staff positions for the National Cancer Institute have increased dramatically, while the total budget request and staffing for the remaining research components of the NIH have been reduced. The full meaning of this situation is not clear, but the Association is nonetheless deeply concerned about its implications because of the Association's concern for the welfare of all of the NIH research programs. In order for the cancer program to be effective, it must have imput from the other bioscience disciplines. If these activities are not adequately staffed and funded, the effectiveness of the cancer program must necessarily be impaired.
>
> The Association and its membership are in agreement that extensive biomedical research efforts are essential if medical science is to discover the causes and to develop cures and treatment for this complex of killer diseases.
>
> The Association has repeatedly stressed that the basic causes and nature of the cancerous process are unknown. The nature of cancer is deeply embedded in the most elemental

> life processes and is an obscure and complex part of the life cycle. Major further progress in the conquest of cancer is, in the final analysis, dependent upon greater understanding of the intricate working of the basic life cell and its responses to both internal and external forces.
>
> It is important to realize that the new leads which seem to offer promise for advances in cancer have emerged in scientific fields which at the same time were far removed from the mainstream of scientific effort in cancer. These new efforts are derived from, and are dependent upon, scientific achievements in the fields of virology, immunology, genetics, and cell biology. No one can predict with certainty the fields from which will come the findings that will provide further insights into the nature of cancer. All bioscientists, however, will agree that real progress in understanding cancer can only come through greater understanding of the fundamental life processes of which it is a part.
>
> The national attack upon cancer cannot be fought exclusively with programs sponsored by the National Cancer Institute. Cancer research is also dependent, in part, upon advances in the various biosciences which are sponsored by the other institutes at the NIH—particularly the general basic research programs of the National Institute of General Medical Sciences.
>
> The Administration's failure to perceive the importance of the other NIH disciplines in the national attack against cancer is evident not only in the lowered budgets of these institutes, but also in the distribution of staff positions within the NIH. Over the past several years, the NIH as a whole has suffered an outright loss of approximately 600 permanent fulltime staff positions. In addition, over 350 more positions have been transferred from the other institutes of the NIH to the NCI and the National Heart and Lung Institute. The net result has been a loss of approximately 950 staff positions within the other institutes of the NIH—a loss which has seriously compromised the ability of the NIH staff to administer the programs under its direction.
>
> The impact of the Administration's decisions on the morale and effectiveness of NIH administrators is clear. The national biomedical research program established by the Congress has been stymied by administrative fiat. The repeated attempts to terminate research training programs, abolish peer review, and reorganize staffing patterns indicate all too clearly that biomedical research and the nation's health do not hold a high priority within this Administration. Such an attitude cannot be allowed to stand unchallenged.

The Secretary of Health, Education and Welfare, the Honorable Caspar W. Weinberger, also testified in respect to the need to maintain the integrity of biomedical research when he stated:

> NCI operations are only one of the avenues of approach. The understanding of the abnormal growth and spread of

> cancer is inextricably linked to the biology of normal cells. The National Cancer Act recognized that, "the present state of our understanding of cancer is a consequence of broad advances across the full scope of the biomedical sciences." This ranges from the molecular biology of genetic control to the biochemistry of cell membranes, metabolism, and immunology. The National Institute of General Medical Sciences, the National Institute of Allergy and Infectious Diseases, the National Institute of Arthritis, Metabolism, and Digestive Diseases, along with the National Cancer Institute and the other Institutes, are responsible for exploring these fundamental life processes through support of basic research. These processes are still far from being fully understood.

Mr. Benno C. Schmidt, Chairman of the President's Cancer Panel, also testified in respect to this problem area when he indicated:

> We have also been deeply concerned about the cuts which have occurred in the budgets of General Medical Sciences, Allergy and Infectious Diseases, Arthritis and Metabolic Diseases, and the other Institutes. Neither the cancer program nor biomedical research in general can thrive if these Institutes are not healthy. At the time we were urging on the Congress and the Administration a greater effort in cancer, we were very explicit in the position that the increased cancer effort should not be at the expense of other biomedical research. I am not sure that the cancer effort has been the cause of these other Institutes receiving less, but it is difficult to prove the contrary when the cuts have in fact taken place. Also, regardless of what would have been the case in other circumstances, the fact is that this country cannot afford to reduce the research efforts of these other Institutes at this time. Therefore, we have urged the Office of Management and Budget to give the highest priority to budget increases for these Institutes. I am hopeful that the Budget for 1975 will include increased appropriations for these Institutes.

The most recent example of the effectiveness of the President's Cancer Panel can be found in a letter from President Nixon to Secretary Weinberger on January 29, 1974, (the day before the Committee's hearings on S. 2893) which states in part:

> I have followed progress on the attack on cancer carefully. In addition, I have met with Benno Schmidt and other members of the President's Cancer Panel and have reviewed their report and the report of the National Cancer Advisory Board with great interest. It is my feeling that considerable progress has been made in the attack on cancer in recent years and that there is much hope for additional knowledge that can be developed in the future.
>
> That is why I plan to ask for an additional $100 million above last year's request of $500 million for the expanded attack on cancer in the budget that I will be submitting to the Congress next Monday. I realize that this will result in spending over $415 million more for this effort next fiscal

> year than was available the year I took office, but I think the dual goals of an expanded research effort to find the causes of cancer along with more intensive demonstration and education programs to help prevent and control cancer warrant this support.

The genesis of the authority for the President's Cancer Panel dates back to the actions of the Committee on Interstate and Foreign Commerce of the House of Representatives in its bill to authorize the establishment of the National Cancer Program of 1971. In its report, 92–659, to accompany H.R. 11302, the House Committee stated:

> The bill provides for a three-man President's Cancer Attack Panel, whose duty it will be to monitor the development of the national cancer attack program and report directly to the President. The Committee recognizes the fact that the President of the United States has many responsibilities and although the attack on cancer is a significant one, it would be impossible for him to follow its progress on a day-by-day basis. Therefore, direct oversight of the program will be accomplished through this panel of highly qualified individuals, who will meet at least twelve times a year, to evaluate the program and make suggestions for improvements, as well as to report directly to the President on any delays or blockages in rapid execution of the program.

> The House Committee also went on to comment:

> The Committee recognizes that cancer, while it is the number one health concern of the American people, is not the only or even the major killer disease. Many eminent scientists have testified that promising leads now existing in cancer research are paralleled in other areas of biomedical research. The strengthening of cancer research should in no way diminish research efforts in other areas of biomedical research.

Biomedical research conducted and supported by the National Institutes of Health has long been recognized as an outstanding American contribution to the worldwide effort against the physical and mental diseases and impairments of man. Recently a number of factors have emerged which threaten the continued excellence of the NIH. Establishment of the President's Biomedical Research Panel is designed to correct those factors.

Within the NIH, problems have arisen in attempts to make effective decisions regarding allocations of resources. Judgments have had to be made for achieving optimum balance within finite resources. Choices have had to be made between individual projects versus multifaceted program projects and centers, between research versus training, between basic research versus applied research and development, between investigator-initiated research versus targeted or NIH-directed programs, between grants versus contracts, between scientific disciplines versus disease categories. In addition, the NIH programs of research have faced increasing difficulties due to such factors as rapidly escalating costs of research and training efforts, increased competition for available funding due to increased numbers of institutions but limited increases in funds, differences of opinion regarding selection of the most appropriate national goals for health, bases for new targeted or directed programs questioned by various sectors of the scientific community, needs for investigators to improve definition and explanation of their work to the satisfaction of broader audiences, and implications of government control inherent in the trend toward forward planning and direction of programs.

The coming together of these problems has resulted in intense pressures on the NIH. These pressures have been aggravated by singling out two of the 12 research institutes and divisions for special national emphasis because of their work with major killer diseases: cancer and heart disease. Targeting special attention on segments of biomedical research—while highly appealing in one sense—disregards the interrelationship of research generally and of advances in knowledge of specific diseases. An example of this is research on diabetes. While the principal NIH Institute responsible for investigating diabetes is the National Institute of Arthritis, Metabolism and Digestive Diseases, numerous other NIH Institutes also conduct and support research directly or generally related to diabetes. Moreover, a key scientific breakthrough in diabetes may come in research totally unrelated to the disease. Thus, a decision to increase funds and staff for the NIAMDD in order to advance a national attack against diabetes might in fact have exactly the opposite effect. The effect might be to set back diabetes research. This is particularly likely if funds and staff for other research institutes and divisions are sacrificed to increase the resources available to the NIAMDD.

The complex set of interconnecting relationships among various fields of biomedical research was perhaps best described by a former NIH Director, Dr. James A. Shannon:

> The inescapable fact is that biomedical science is a complex, interrelated, n-dimensional universe. One can wish it were not, but it is. True, there are within it some large confluences of great density, such as cancer, but even this is inseparable from other large islands such as aging, human development, etc., which in turn relate to arteriosclerosis and stroke. To look at any isolated fragment, no matter how large, apart from its innumerable major and minor connections in the vast network of relationships, would be at best naive and at worst selfdefeating. This reality animates the processes that the scientific community has institutionalized in the NIH, to view biomedical sciences, to the extent possible, holistically and thereby to assess opportunities not in isolation but in the context of the past state of the art and recent changes in contiguous domains of science.

Since enactment of the National Cancer Act of 1971 and of the National Heart, Blood Vessel, Lung and Blood Act of 1972, there has been a measurable shift in the NIH research effort. Instead of advances over the broad front of NIH research activities, the NIH generally has stood still, while the National Cancer Institute and the National Heart and Lung Institute have surged ahead. Comparisons of fiscal 1972 appropriations and the fiscal 1975 budget requests illustrate the point. Funding for the National Cancer Institute is up 61 percent. Funding for the National Heart and Lung Institute is up 37 percent. Funding for all other research institutes and divisions is down $2.3 million. NIH staffing levels tell a similar tale. Over the past several years the NIH as a whole has been forced to cut back some 600 permanent full-time staff positions. In addition, more than 350 additional positions have been transferred from other institutes and divisions to the NCI and the NHLI. The net result has been a loss of approximately 950 staff positions within the other institutes of the NIH—a loss which has seriously compromised the ability of the NIH staff to administer the programs under its direction. These decisions have been ordered and approved by the Office of Management and Budget, despite its lack of staff experts in biomedical research. The OMB professional staff does not include a single physician or PhD in the biological sciences.

The President's Biomedical Research Panel is designed to deal with these problems before they further disrupt the nation's biomedical research effort. The Panal is to monitor the complete range of research activities of the NIH. Recognizing the indivisible, unitary nature of biomedical research, the Panel is to assess the research programs of the various institutes and divisions in light of the available resources and of the scientific opportunities across the whole front of biomedical science. The Panel is to have direct access to the President and is to identify for his consideration and possible action any problems that threaten the coherent development and prosecution of an effective biomedical research effort. The Panel is to be particularly mindful of presently identified problems and is to be alert to, and shall be responsible for identifying as rapidly as possible, the development of new problems which threaten or may threaten the continued excellence of the National Institutes of Health.

The Committee recommends that the President, in selecting the appointed members of the President's Biomedical Research Panel, solicit the names of appropriate candidates from groups of experts in the scientific and biomedical fields, such as the National Academy of Sciences.

The Committee's recommendation for establishment of a President's Biomedical Research Panel stems in part from experience under the National Cancer Act, since the growth of the cancer program has clearly been at the expense of other NIH research activities. More importantly, however, it represents the Committee's concern that the present Administration does not understand the importance of a balanced, stable biomedical research program, and that the consequences of this misunderstanding will be far reaching and difficult to remedy.

The Panel of Consultants on the Conquest of Cancer emphasized in its initial report to this Committee that while a national cancer program would demand additional resources, "It is of utmost importance that the financing of this program not result in cutbacks in other health programs." Yet the present Administration has in effect reduced the resources available to other NIH Institutes (except the National Heart and Lung Institute). A major task of the new panel will be to call to the President's attention the consequences of such shortsighted policies, and to inform the Congress—and the public—of obstacles to continued progress across the broad spectrum of biomedical research for which NIH is responsible.

A broader issue to which this provision is addressed is the unavailability of scientific expertise and advice to those Administration officials who make the ultimate decisions about funding and program emphasis in health research. The dissolution of the White House science advisory apparatus has left a major gap in the chain of advice and command affecting NIH programs. The Committee feels that the decisions affecting the level and direction of NIH efforts are far too complex to be treated simply as part of "health," "HEW," or even "human resources" budgets. What is needed is a strengthening of the *interpretive* process, through which the demands of scientific inquiry and management of the nation's resources are melded into responsible public policy. At present the "health" dimension of NIH activities is reviewed at higher levels in reasonably responsible fashion, but there is no voice for the underlying and essential science dimension, as may be seen by an examination of NIH budget and staffing patterns over the last five years.

No responsible scientific investigator, at NIH or elsewhere, would deny that the ultimate goal of publicly supported biomedical research is to improve the health of our citizens. The Administration and the Congress have become increasingly concerned—and properly so—with the quality and availability of health services. The Committee notes with regret, however, that the Department appears to be ignoring the warning of the NIH that service needs ". . . should not be viewed as competitive with those of the research programs which have made them possible. . . . The goose and the golden egg—medical research and health services—are not alternatives. They are a continuing sequence essential to the progress and well-being of man." (*The Advancement of Knowledge for the Nation's Health: A Report to the President on the Research Programs of the National Institutes of Health,* 1967).

Despite this warning, the various HEW organizational arrangements have traditionally lumped together all "health" programs, so that research in effect does compete with service programs, and the first level of Departmental analysis involves budget trade-offs that are inherently exchanges of non-commensurable quantities. Even more disturbing is the fact that NIH funds constitute a highly visible and substantial proportion of the shrinking HEW "controllable" budget, so that biomedical research has become increasingly vulnerable.

The point to be made is not that other HEW programs are not meritorious, but that level of the nation's biomedical research effort is measured not by a single year's budget, but by the quality of the institutions and individuals performing the research. The Committee believes that this Administration, in its laudable concern for reexamination of the proper Federal role in many areas of national life, has overlooked the importance of stable support and reasonable program growth in the maintenance of a pool of excellent institutions and talented investigators. The Committee hopes that the panel will be able to articulate the importance of maintaining and strengthening the nation's biomedical resources.

It is significant that the initiative for Federal medical research—beginning with establishment of the NCI in 1937—has traditionally come from the Congress, as has the concern for the long-range well-being of the biomedical research enterprise. The Committee intends that the panel will strengthen the Executive's capacity to assess the long-term needs of biomedical research. Certainly both Branches will have an even greater need for the long view as they continue to work to resolve the related—but fundamentally different-issues of the financing and organization of health care.

The panel's specific task is to appraise the biomedical research program of the NIH. However, the Committee believes that the panel could play a number of additional, useful roles. For example, it could add its advice to the process by which NIH identifies areas of scientific inquiry suitable for increased emphasis. It could also serve to promote coordination of related research by NIH and other agencies. Certainly the Committee intends that its evaluation of NIH research take place in the context of all Federally supported biomedical research.

The Committee is aware that performance of the panel's task will require considerable staff support. The Committee expects that the Director of NIH, will provide the needed support and that sufficient *new* positions will be made available to him for this purpose.

At the time the Committee met in executive session to take final action on S. 2893, the Acting Secretary of the Department of HEW, the Honorable Frank Carlucci, wrote to the Committee expressing the Department's objections to S. 2893. Specifically with respect to the President's Biomedical Research Panel, he stated:

> Dear Mr. Chairman: It is our understanding that the full Labor and Public Welfare Committee will hold an executive session in the near future on several bills which are of considerable interest to the Department. Many features of these bills are desirable and have our support. But we strongly oppose certain provisions which have been included by the Health Subcommittee or are expected to be considered in the full Committee. This letter will explain briefly our opposition to certain undesirable features of these bills.
>
> *S. 2893—Extension of Cancer Research Authority*
>
> The Administration supports extension of the authority for the expanded cancer research effort, and we so testified before the Senate Health Subcommittee on January 31, 1974. However, the bill which has been reported to the full Committee includes the provisions of a separate bill, S. 3023, raising entirely new issues. S. 3023 would establish a three-member Presidentially appointed panel (the President's Biomedical Research Panel) to oversee the biomedical research activities carried on by the National Institutes of Health (including the National Cancer Institute). The Panel would report directly to the President and could bring to the attention of the Congress directly any "delays or blockages in rapid execution of the biomedical research programs of the National Institutes of Health."

> I believe that the National Institutes of Health are well-run and well-managed, and that their programs are easily accessible to Congressional oversight and review. I do not believe that the establishment of a Presidentially appointed Panel would either enhance Congressional control or aid in the administration of the health programs of HEW. To the contrary, it would make program administration more complicated and inefficient. Moreover, the proposed dual reporting relationship cannot but result in undermining the responsibilities of the HEW Secretary and the Assistant Secretary for Health.
>
> For these reasons, I strongly oppose the creation of such a Presidential Panel. I would feel constrained if S. 2893 is sent to the President with provisions for such a Panel to recommend to the President that he veto that bill, in spite of our strong support for an extension of the cancer research authority.

In recognition of this serious challenge by the administration the Committee voted on the question and in a roll call vote unanimously endorsed the inclusion of the authority for the President's Biomedical Research Panel as Title II of S. 2893.

The Committee believes that it is in the Nation's interest for this panel to come into existence as quickly as possible. The Committee does not believe it is in the Nation's interest, if the President were to veto the National Cancer Act of 1974.

B. *Availability of Funds*

The Medical Facilities Construction and Modernization Amendment of 1970 (the 1970 Hill-Burton amendment) contained a provision designed to assure the availability and expenditure of appropriated health funds. This provision, unless amended, would expire on the first of July, 1974. S. 2893 would permanently extend it. The Committee has felt it appropriate to do this in view of the recent Administration record of impoundment of funds and the Administration's express desire to terminate many health programs prior to Congressional review of them.

The provision which requires obligation and expenditure of the appropriated funds is Section 601 of the Medical Facilities Construction and Modernization Amendments of 1970 (P.L. 91–296), 42 U.S.C.A. §§ 201 note and 2661 note ("Section 601"). Section 601 reads as follows:

> Notwithstanding any other provision of law, unless enacted after the enactment of this Act expressly in limitation of the provisions of this section, funds appropriated for any fiscal year ending prior to July 1, 1973, to carry out any program for which appropriations are authorized by the Public Health Service Act (Public Law 410, Seventy-eighth Congress, as amended) or the Mental Retardation Facilities and Community Mental Health Centers Construction Act of 1963 (Public Law 88–164, as amended) shall remian available for obligation and expenditure until the end of such fiscal year.

Section 601 has been understood by the Congress, as preventing any withholding of appropriated funds. The Section was initially inserted into the bill which became the Medical Facilities Construction and Modernization Amendments of 1970 by the Senate. Although there was no comment regarding Section 601 when passed by the Senate, the subsequent Conference Report stated as follows:

> AVAILABILITY OF APPROPRIATIONS
>
> The Senate amendment would have provided that funds appropriated for any fiscal year to carry out any program under the Public Health Service Act, the Mental Retardation Facilities and Community Mental Health Centers Construction Act of 1963, certain acts relating to Indian health programs, the Vocational Rehabilitation Act, the Clean Air Act, the Solid Waste Disposal Act, and Title V of the Social Security Act would remain available for obligation and expenditure until the end of the fiscal year for which appropriated.
>
> The conference substitute is the same as the Senate amendment, except that it is limited to funds appropriated for fiscal years ending before July 1, 1973, and applies only to funds appropriated to carry out programs under the Public Health Service Act or the Mental Retardation Facilities and Community Mental Health Centers Construction Act of 1963. The purpose of the amendment is to prevent administration imposed freezes, reductions and rollbacks from applying to health programs authorized under these Acts. Where a program authorizes availability of appropriations for more than one fiscal year, the conferees intend that the amendment shall apply to the entire period covered by the appropriations.

After passage of the bill, it was vetoed by the President on June 22, 1970. He stated in his veto message:

> One of the most unacceptable provisions of the bill is in Section 601. Here, the Congress insists that funds appropriated for any fiscal year through 1973 to carry out the programs involved must be spent. In addition to restricting flexibility in management of federal expenditures, this provision would interfere with my ability to comply with the limitation on total 1971 spending that has already passed the House of Representatives and has been reported by the Senate Appropriations Committee. The amount of money involved is large; Section 601 would affect $2.5 billion of my budget request for the Department of Health, Education and Welfare for 1971. This kind of provision puts the Congress in the position of withdrawing with one hand the authority necessary to do what it requires with the other. I ask the Congress to eliminate Section 601.

With this common understanding as basis for action, the House and Senate each overrode the Presidential veto on June 25 and 30, 1970, respectively.

Section 601 was then scheduled to expire June 30, 1973. Last year the Congress extended the authority for an additional year as a part of the Public Health Service Extension Act of 1973, Public Law 93–45.

In summary, it is unarguable that, assuming there have been public moneys validly appropriated, Section 601 mandates that such funds must be obligated and expended.

There was no general appropriation act enacted by Congress for fiscal year 1973 for the programs administered by the Department of Health, Education and Welfare; although Congress on two occasions passed fiscal year 1973 appropriations acts for DHEW (H.R. 15417, H.R. 16654, 92nd Cong., 2d Sess. (1972), both were vetoed by the President. Thus the Congress enacted (and the President signed) a continuing resolution appropriating funds for such agencies, H.J. Res. 1234, 92nd Cong., 2d Sess. (1972), Public Law 92–334, which was extended four times to cover the entire fiscal year 1973.

Although Congress appropriated funds for the DHEW health programs for fiscal year 1973 and under Section 601 mandated the obligation and expenditure of all of such funds, the Secretary refused to obligate and expend the entirety of such funds, claiming that the need to control federal spending in order to curtail the rate of inflation and eliminate the need for a tax increase requires cutbacks in these particular programs, which he has characterized as either ineffective or nonessential. As a result, a number of legal actions were instituted, relying on the authority of Section 601, to force the release of the impounded health funds for obligation and expenditure. The legal actions were uniformly successful, and on December 19, 1973, President Nixon announced the release of all impounded funds, whether subject to legal actions or not. Section 601 clearly served an important function in this series of actions.

A summary of the legal actions brought under Section 601 is listed below:

> *National League for Nursing* v. *Ash* (D.D.C., C.A. No. 1316–73). Preliminary injunction entered July 10, 1973, requiring HEW to record as a Fiscal Year 1973 obligation the $21.7 million balance of the $38.5 million appropriated for grants to nursing schools. Final order entered November 19, 1973, requiring obligation and expenditure of funds.
>
> *American Association of Colleges of Podiatric Medicine* v. *Ash* (D.D.C., C.A. No. 1139–73), consolidated with:
>
> *American Association of Colleges of Pharmacy* v. *Ash* (D.D.C., C.A. No. 1244–73). (Association of Schools and Colleges of Optometry permitted to intervene as plaintiff.) Preliminary injunction entered June 27, 1973, requiring HEW to record as an obligation for Fiscal Year 1973 the unallotted balance of funds appropriated from grants to Schools of Podiatry, Pharmacy, and Optometry. On October 26, 1973, the court granted plaintiffs' motion for summary judgment requiring the allotment of $9,914,327.
>
> *Eastern Virginia Medical School* v. *Weinberger* (E.D. Va., C.A. No. 73–315–N). Plaintiff seeks the allotment of $240,000 for Fiscal Year 1973 and $180,000 for Fiscal Year 1974. The

statute involved is 42 U.S.C. 295f–1(a), concerning start-up assistance to schools of medicine, osteopathy, and dentistry. Plaintiff moved for summary judgment on November 1, 1973. Defendants answered on October 8, 1973.

*Association of American Medical Colleges* v. *Weinberger* (D.D.C., C.A. No. 1794–73 and 1830–73, consolidated). No. 1794–73 involves special project grants to medical schools under 42 U.S.C. 295f–2 (approximately $28.6 million at issue). No. 1830–73 concerns research grants, research training grants and fellowships to medical schools under 42 U.S.C. 241 and 242f (approximately $112.5 million is involved). On October 26, 1973, the court granted plaintiffs' motion for a preliminary injunction and granted a final judgment in favor of plaintiffs.

*National Council of Community Mental Health Centers, Inc.* v. *Weinberger* (D.D.C., C.A. No. 1223–73). Plaintiff's motion for summary judgment granted on August 3, 1973, requiring the obligation of approximately $50 million.

*National Association for Mental Health, Inc.* v. *Weinberger* (D.D.C., C.A. No. 1812–73). Plaintiff's motion for TRO denied on September 28, 1973.

*National Association of Regional Medical Programs, et. al.* v. *Weinberger* (D.D.C., C.A. No. 1807–73).

The Committee continues to strongly believe that the continuation of Section 601 is essential to assure the allocation, obligation, and expenditure of funds appropriated pursuant to the authorities of the Public Health Service Act and the Mental Retardation Facilities and Community Mental Health Centers Act of 1963.

### C. *Need for Additional Comprehensive Cancer Centers*

The Committee, as well as the vast majority of witnesses who testified before it, believes that to effectively implement Section 408(a), provision must be made to permit the designation of more than the 15 new Comprehensive Cancer Centers stipulated in the National Cancer Act of 1971. The question has been, how many Comprehensive Centers are needed to reach the greatest number of Americans without wasting valuable resources. Testimony delivered before the Committee indicates that based on population studies which have been carried out to determine the potential impact of Comprehensive Centers based on geographic distribution, a total of 35 would provide access to 75 percent of the population without requiring an overnight stay. Additional centers beyond this number would not substantially increase the potential access to Comprehensive Center programs. The Committee believes that no American should be denied first class cancer care simply because of where he may live. Equity demands that this limitation on the number of high quality cancer centers be removed.

### D. *Need to Facilitate Administrative Management*

The Director of the National Cancer Program must be able to plan, manage, organize and assess the activities of the program with sufficient flexibility to maximize the program's efforts. The Committee is aware that a program the size and scope of the National Cancer Program will inherently have administrative requirements that, despite the soundness of the managerial theories involved, will create delays in implementation. Therefore, the Committee recommends the following changes in the law to allow the Director, NCI, additional latitude in the management of the program.

(1) The inclusion of indirect costs in the computation of $35,000 grants that the Director, NCI, can award without review and recommendation of the National Cancer Advisory Board. In fiscal 1973, as an example, the number of proposals eligible for funding under this provision would have been 258 instead of 179, permitting the Director to award those additional 79 prior to NCAB recommendation. This would save as much as two months from the usual time required in making an award.

(2) The striking out of the phrase "where appropriate" in Section 407(b)(7) to assure the continued supply of high quality cancer researchers.

(3) The inclusion of a provision to permit the NCI Director to award grants for new construction as well as alterations and renovations for improvement of basic research laboratory facilities, including those related to biohazard control.

(4) The increase of the number of consultant/expert appointments available to the NCI from 50 to 100 with specific recommendation to exclude these appointments from the regular position ceilings assigned to the NCI by the DHEW and NIH.

### E. *Information Services*

The Committee is concerned about the loss of the independent authorities of the Director, NCI, to conduct a full range of communications, information and public affairs activities in support of the National Cancer Program. These authorities are important to the effective implementation of the Act, and are not to be subject to regulation or modification within the DHEW. Testimony before the Committee indicates such regulations, guidelines and rules do exist and therefore the Committee's bill offers new provisions to provide independence for the Director in this regard.

Although no specific changes in the law are included concerning Section 407(b)(4), the establishment of an International Cancer Research Data Bank, the Committee believes its information services amendment strengthens the ability of the NCI Director to fully implement this program and will watch the development of the program carefully over the three-year extension of the National Cancer Act.

Concern was expressed by the Committee as to the implementation of Section 407(b)(4), the establishment of an International Cancer Research Data Bank, and the development of a system for making its contents available to researchers from all nations.

The Committee was not satisfied with the Administration's testimony in this respect. The intent of Congress in this section was to establish a central system by which the Cancer research effort would be substantially assisted through the systematic storage of all Cancer research data, including information on past and present, successful and unsuccessful research projects.

Because the ICRDB would fully integrate information from all sources, it would facilitate and promote the exchange of Cancer research information among scientists and clinicians on a world wide basis. To date, the primary activities of the ICRDB project have been limited only to the identification of specific gaps in the existing information services systems throughout the world, and to the tentative development of products and services to fill these gaps.

While these tasks are properly part of the eventual building process, the Committee firmly believes that a concentrated and redirected effort must be made to bring together under a single roof the information in these scattered resource repositories, and to make their relevant contents fully and quickly retrievable with a single inquiry.

The Committee expects the National Cancer Institute to redirect its efforts and to make substantive progress to implement the clear directive of Section 407(b)(4) but with understanding and appreciation for prudent fiscal management.

## V. Cost Estimates Pursuant to Section 252 of the Legislative Reorganization Act of 1970

In accordance with Section 252(a) of the Legislative Reorganization Act of 1970 (Public Law 91–510, 91st Congress) the Committee estimates that the cost which would be incurred in carrying out this bill is as follows:

NEW OBLIGATIONAL AUTHORITY FOR FISCAL YEARS 1975, 1976, AND 1977 UNDER S. 2893

[In millions of dollars]

| | Fiscal year— | | |
|---|---|---|---|
| | 1975 | 1976 | 1977 |
| National cancer program | 750 | 830 | 985 |
| Cancer control program | 50 | 65 | 85 |
| Total | 800 | 895 | 1,070 |

## VI. Tabulation of Votes Cast in Committee

Pursuant to section 133(b) of the Legislative Reorganization Act of 1949, as amended, the following is a tabulation of votes in Committee:

Motion to lay on the table the motion to delete Title II of the bill, thereby retaining the proposed authority respecting the establishment of a Presidential Biomedical Research Panel.

| Yeas—16 | Nays—0 |
|---|---|
| Senator Williams | |
| Senator Randolph | |
| Senator Pell | |
| Senator Kennedy | |
| Senator Nelson | |
| Senator Mondale | |
| Senator Eagleton | |
| Senator Cranston | |
| Senator Hughes | |
| Senator Hathaway | |
| Senator Javits | |
| Senator Dominick | |
| Senator Schweiker | |
| Senator Taft | |
| Senator Beall | |
| Senator Stafford | |

Motion to favorably report the bill to the Senate carried unanimously by voice vote.

## VII. Section by Section Analysis of S. 2893

Section 2 of the bill amends Section 301(h) of the Public Health Service Act so as to permanently extend the expiring authority of the National Institutes of Health to let research contracts.

Section 3 amends Section 402(b) of the Public Health Service Act to require that only direct costs be included in the determination respecting whether National Cancer Institute grants are in excess of $35,000, thereby requiring peer review.

Section 4 amends Section 407(b) of the Act in the following ways:

1. By requiring the use of training stipends, fellowships, and career awards in the training of manpower in fundamental sciences and clinical disciplines respecting cancer.
2. By including where appropriate nutritional programs for persons under treatment for cancer in the National Cancer Institute's data systems, and
3. By requiring the inclusion of the number and types of personnel necessary to carry out the National Cancer Program in the submission of the annual budget estimate for the Program to the President.
4. By including a new paragraph 10 which requires the Director of the National Cancer Institute to conduct or contract for programs to disseminate and interpret information respecting cancer.

Section 5 amends Section 408(a) by removing the limitation respecting the establishment of new centers for clinical research, training and demonstration of advanced diagnostic and treatment methods relating to cancer.

Section 6 amends Section 409(b) by extending the authorization for the Cancer Prevention and Control Program through 1977 as follows:

1975—$50 million.
1976—$65 million.
1977—$85 million.

Section 7 amends Section 410 by—

1. Increasing the number of consultants the Director of the National Cancer Institute may call upon from 50 to 100, and
2. Including authorization to award grants for new construction as well as alterations and renovations for improvement of basic research laboratory facilities, including those related to biohazard control.

Section 8 amends Section 410A(a) by subjecting contracts to peer review.

Section 9 amends Section 410C of the Public Health Service Act to extend the authorization for appropriations for the National Cancer Program for an additional three years through 1977 as follows:

1975—$750 million.
1976—$830 million.
1977—$985 million.

Section 10 amends Part A of Title IV of the Public Health Service Act by adding at the end thereof a new Section 410D which permanently extends the expiring Section 601 of PL 91–296 respecting the availability of appropriations.

Section 11 amends Section 454 of the Public Health Service Act to require the advice and consent of the Senate respecting the appointment of the Director of the National Institutes of Health.

Section 201 amends Title IV of the Public Health Service Act by adding at the end thereof new Section 455 which establishes the President's Biomedical Research Panel to be composed of the Chairman of the President's Cancer Panel and four members appointed by the President who are exceptionally qualified to appraise the biomedical research program of the National Institutes of Health (including the research program of the National Institute of Mental Health). At least three members of the Panel shall be distinguished scientists or physicians. The Panel shall monitor the development and execution of the biomedical research programs of the National Institutes of Health and shall report directly to the President. Any delays or blockages in the rapid execution of the biomedical research programs of the National Institutes of Health shall immediately be brought to the attention of the President and the Congress. At the request of the President, the Panel shall submit for his consideration a list of names of persons for consideration for appointment as Director of the National Institutes of Health.

## VIII. Changes in Existing Law

In compliance with subsection (4) of Rule XXIX of the Standing Rules of the Senate, changes in existing law made by the bill as repeated are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

## PUBLIC HEALTH SERVICE ACT

* * * * * * *

## TITLE III—GENERAL POWERS AND DUTIES OF PUBLIC HEALTH SERVICE

### PART A—RESEARCH AND INVESTIGATION

* * * * * * *

(h) Enter into contracts [during the fiscal year ending June 30, 1966, and each of the eight succeeding fiscal years,] including contracts for research in accordance with and subject to the provisions of law applicable to contracts entered into by the military departments under title 10, United States Code, sections 2353 and 2354, except that determination, approval, and certification required thereby shall be by the Secretary of Health, Education, and Welfare; and

* * * * * * *

(b) Under procedures approved by the Director of the National Institutes of Health, the Director of the National Cancer Institute may approve grants under this Act for cancer research or training—

(1) [in amounts not to exceed $35,000] *if the direct costs of such research and training do not exceed $35,000, but only* after appropriate review for scientific merit but without the review and recommendation by the National Cancer Advisory Board prescribed by section 403(c), and

(2) [in amounts exceeding $35,000] *if the direct costs of such research and training exceed $35,000, but only* after appropriate review for scientific merit and recommendation for approval by such Board as prescribed by section 403(c).

* * * * * * *

### NATIONAL CANCER PROGRAM

SEC. 407. (a) The Director of the National Cancer Institute shall coordinate all of the activities of the National Institutes of Health relating to cancer with the National Cancer Program.

(b) In carrying out the National Cancer Program, the Director of the National Cancer Institute shall:

(1) With the advice of the National Cancer Advisory Board, plan and develop an expanded, intensified, and coordinated cancer research program encompassing the programs of the National Cancer Institute, related programs of the other research institutes, and other Federal and non-Federal programs.

(2) Expeditiously utilize existing research facilities and personnel of the National Institutes of Health for accelerated exploration of opportunities in areas of special promise.

(3) Encourage and coordinate cancer research by industrial concerns where such concerns evidence a particular capability for such research.

(4) Collect, analyze, and disseminate all data (*including where appropriate nutritional programs for persons under treatment for cancer*) useful in the prevention, diagnosis, and treatment of cancer, including the establishment of an international cancer research data bank to collect, catalog, store, and disseminate insofar as feasible the results of cancer research undertaken in any country for the use of any person involved in cancer research in any country.

(5) Establish or support the large-scale production or distribution of specialized biological materials and other therapeutic substances for research and set standards of safety and care for persons using such materials.

(6) Support research in the cancer field outside the United States by highly qualified foreign nationals which research can be expected to inure to the benefit of the American people; support collaborative research involving American and foreign participants; and support the training of American scientists abroad and foreign scientists in the United States.

(7) Support appropriate manpower programs of training in fundamental sciences and clinical disciplines to provide an expanded and continuing manpower base from which to select investigators, physicians, and allied health professions personnel, for participation in clinical and basic research and treatment programs relating to cancer, including **[**where appropriate**]** the use of training stipends, fellowships, and career awards.

(8) Call special meetings of the National Cancer Advisory Board at such times and in such places as the Director deems necessary in order to consult with, obtain advice from, or to secure the approval of projects, programs, or other actions to be undertaken without delay in order to gain maximum benefit from a new scientific or technical finding.

(9)(A) Prepare and submit, directly to the President for review and transmittal to Congress, an annual budget estimate for the National Cancer Program, *including the number and types of personnel necessary to carry out such program*, after reasonable opportunity for comment (but without change) by the Secretary; the Director of the National Institutes of Health, and the National Cancer Advisory Board; and (B) receive from the President and the Office of Management and Budget directly all funds appropriated by Congress for obligation and expenditure by the National Cancer Institute, *and the allocation of personnel requested to carry out the National Cancer Program.*

*(10) The Director of the National Cancer Institute shall conduct or contract for programs to disseminate and interpret on a current basis for practitioners and other health professionals, scientists, and the general public, scientific and other information respecting the cause, prevention, diagnosis and treatment of the disease or other health problem to which the activities of the Institute are directed. The Director of the National Cancer Institute shall issue such regulations as are necessary to carry out this activity.*

(c)(1) There is established the President's Cancer Panel (hereinafter in this section referred to as the "Panel") which shall be composed of three persons appointed by the President, who by virtue of their training, experience, and background are exceptionally qualified to appraise the National Cancer Program. At least two of the members of the Panel shall be distinguished scientists or physicians.

(2) (A) Members of the Panel shall be appointed for three-year terms, except that (i) in the case of two of the members first appointed, one shall be appointed for a term of one year and one shall be appointed for a term of two years, as designated by the President at the time of appointment, and (ii) any member appointed to fill a vacancy occurring prior to the expiration of the term for which his predecessor was appointed shall be appointed only for the remainder of such term.

(B) The President shall designate one of the members to serve as Chairman for a term of one year.

(C) Members of the Panel shall each be entitled to receive the daily equivalent of the annual rate of basic pay in effect for grade GS–18 of the General Schedule for each day (including traveltime) during which they are engaged in the actual performance of duties vested in the Panel, and shall be allowed travel expenses (including a per diem allowance) under section 5703(b) of title 5, United States Code.

(3) The Panel shall meet at the call of the Chairman, but not less often than twelve times a year. A transcript shall be kept of the proceedings of each meeting of the Panel, and the Chairman shall make such transcript available to the public.

(4) The Panel shall monitor the development and execution of the National Cancer Program under this section, and shall report directly to the President. Any delays or blockages in rapid execution of the Program shall immediately be brought to the attention of the President. The Panel shall submit to the President periodic progress reports on the Program and annually an evaluation of the efficacy of the Program and suggestions for improvements, and shall submit such other reports as the President shall direct. At the request of the President, it shall submit for his consideration a list of names of persons for consideration for appointment as Director of the National Cancer Institute.

## NATIONAL CANCER RESEARCH AND DEMONSTRATION CENTERS

SEC. 408. (a) The Director of the National Cancer Institute is authorized to provide for the establishment of [fifteen] new centers for clinical research, training, and demonstration of advanced diagnostic and treatment methods relating to cancer. Such centers may be supported under subsection (b) or under any other applicable provision of law.

(b) The Director of the National Cancer Institute, under policies established by the Director of the National Institutes of Health and after consultation with the National Cancer Advisory Board, is authorized to enter into cooperative agreements with public or private nonprofit agencies or institutions to pay all or part of the cost of planning, establishing, or strengthening, and providing basic operating support for existing or new centers (including, but not limited to, centers established under subsection (a)) for clinical research, training, and demonstration of advanced diagnostic and treatment methods relating to cancer. Federal payments under this subsection in support of such cooperative agreements may be used for (1) construction (notwithstanding any limitation under section 405), (2) staffing and other basic operating costs, including such patient care costs as are required for research, (3) training (including training for allied health professions personnel), ad (4) demonstration purposes; but support under this subsection (other than support for construction) shall not exceed $5,000,000 per year per center. Support of a center under this section may be for a period of not to exceed three years and may be extended by the Director of the National Cancer Institute for additional periods of not more than three years each, after review of the operations of such centers by an appropriate scientific review group established by the Director of the National Cancer Institute.

## CANCER CONTROL PROGRAMS

SEC. 409. (a) The Director of the National Cancer Institute shall establish programs as necessary for cooperation with State and other health agencies in the diagnosis, prevention, and treatment of cancer.

(b) There are authorized to be appropriated to carry out this section $20,000,000 for the fiscal year ending June 30, 1972, $30,000,000 for the fiscal year ending June 30, 1973, [and] $40,000,000 for the fiscal year ending June 30, 1974, *$50,000,000 for the fiscal year ending June 30, 1975, $65,000,000 for the fiscal year ending June 30, 1976, and $85,000,000 for the fiscal year ending June 30, 1977.*

## AUTHORITY OF DIRECTOR

SEC. 410. The Director of the National Cancer Institute (after consultation with the National Cancer Advisory Board), in carrying out his functions in administering the National Cancer Program and without regard to any other provision of this Act, is authorized—

(1) if authorized by the National Cancer Advisory Board, to obtain (in accordance with section 3109 of title 5, United States Code, but without regard to the limitation in such section on the number of days or the period of such service) the services of not more than [fifty] *one hundred* experts or consultants who have scientific or professional qualifications;

(2) to acquire, construct, improve, repair, operate, and maintain cancer centers, laboratories, research, and other necessary facilities and equipment, and related accommodations as may be necessary, and such other real or personal property (including patents) as the Director deems necessary; to acquire, without regard to the Act of March 3, 1877 (40 U.S.C. 34), by lease or otherwise through the Administrator of General Services, buildings or parts of buildings in the District of Columbia or communities located adjacent to the District of Columbia for the use of the National Cancer Institute for a period not to exceed ten years;

(3) to appoint one or more advisory committees composed of such private citizens and officials of Federal, State, and local governments as he deems desirable to advise him with respect to his functions;

(4) to utilize, with their consent, the services, equipment, personnel, information, and facilities of other Federal, State, or local public agencies, with or without reimbursement therefor;

(5) to accept voluntary and uncompensated services;

(6) to accept unconditional gifts, or donations of services, money, or property, real, personal, or mixed, tangible or intangible;

(7) to enter into such contracts, leases, cooperative agreements, or other transactions, without regard to sections 3648 and 3709 of the Revised Statutes of the United States (31 U.S.C. 529, 41 U.S.C. 5), as may be necessary in the conduct of his functions, with any public agency, or with any person, firm, association, corporation, or educational institutions; **[and]**

(8) to take necessary action to insure that all channels for the dissemination and exchange of scientific knowledge and ininformation are maintained between the National Cancer Institute and the other scientific, medical, and biomedical disciplines and organizations nationally and internationally **[.]** *; and to award grants for new construction as well as alterations and renovations for improvement of basic research laboratory facilities, including those related to biohazard control, as deemed necessary for the National Cancer Program.*

### SCIENTIFIC REVIEW; REPORTS

Sec. 410A. (a) The Director of the National Cancer Institute shall, by regulation, provide for proper scientific review of all research grants, *contracts*, and programs over which he has authority (1) by utilizing, to the maximum extent possible, appropriate peer review groups established within the National Institutes of Health and composed principally of non-Federal scientists and other experts in the scientific and disease fields, and (2) when appropriate, by establishing, with the approval of the National Cancer Advisory Board and the Director of the National Institutes of Health, other formal peer review groups as may be required.

(b) The Director of the National Cancer Institute shall, as soon as practicable after the end of each calendar year, prepare in consultation with the National Cancer Advisory Board and submit to the President for transmittal to the Congress a report on the activities, progress, and accomplishments under the National Cancer Program during the preceding calendar year and a plan for the Program during the next five years.

### NATIONAL CANCER ADVISORY BOARD

Sec. 410B. (a) There is established in the National Cancer Institute a National Cancer Advisory Board (hereinafter in this section referred to as the "Board") to be composed of twenty-three members as follows:

(1) The Secretary, the Director of the Office of Science and Technology, the Director of the National Institutes of Health, the chief medical officer of the Veterans' Administration (or his

designee), and a medical officer designated by the Secretary of Defense shall be ex officio members of the Board.

(2) Eighteen members appointed by the President. Not more than twelve of the appointed members of the Board shall be scientists or physicians and not more than eight of the appointed members shall be representatives from the general public. The scientists and physicians appointed to the Board shall be appointed from persons who are among the leading scientific or medical authorities outstanding in the study, diagnosis, or treatment of cancer or in fields related thereto. Each appointed member of the Board shall be appointed from among persons who by virtue of their training, experience, and background are especially qualified to appraise the programs of the National Cancer Institute.

(b) (1) Appointed members shall be appointed for six-year terms, except that of the members first appointed six shall be appointed for a term of two years, and six shall be appointed for a term of four years, as designated by the President at the time of Appointment.

(2) Any member appointed to fill a vacancy occurring prior to expiration of the term for which his predecessor was appointed shall serve only for the remainder of such term. Appointed members shall be eligible for reappointment and may serve after the expiration of their terms until their successors have taken office.

(3) A vacancy in the Board shall not affect its activities, and twelve members thereof shall constitute a quorum.

(4) The Board shall supersede the existing National Advisory Cancer Council, and the appointed members of the Council serving on the effective date of this section shall serve as additional members of the Board for the duration of their terms then existing or, for such shorter time as the President may prescribe.

(c) The President shall designate one of the appointed members to serve as Chairman for a term of two years.

(d) The Board shall meet at the call of the Director of the National Cancer Institute or the Chairman, but not less often than four times a year and shall advise and assist the Director of the National Cancer Institute with respect to the National Cancer Program.

(e) The Director of the National Cancer Institute shall designate a member of the staff of the the Institute to act as Executive Secretary of the Board.

(f) The Board may hold such hearings, take such testimony, and sit and act at such times and places as the Board deems advisable to investigate programs and activities of the National Cancer Program.

(g) The Board shall submit a report to the President for transmittal to the Congress not later than January 31 of each year on the progress of the National Cancer Program toward the accomplishment of its objectives.

(h) Members of the Board who are not officers or employees of the United States shall receive for each day they are engaged in the performance of the duties of the Board compensation at rates not to exceed the daily equivalent of the annual rate in effect for GS–18 of the General Schedule, including traveltime; and all members, while so serving away from their homes or regular places of business, may be allowed travel expenses, including per diem in lieu of subsistence, in the same manner as such expenses are authorized by section 5703, title 5, United States Code, for person in the Government service employed intermittently.

(i) The Director of the National Cancer Institute shall make available to the Board such staff, information, and other assistance as it may require to carry out its activities.

### AUTHORIZATION OF APPROPRIATIONS

Sec. 410C. For the purpose of carrying out this part (other than section 409), there are authorized to be appropriated $400,000,000 for the fiscal year ending June 30, 1972; $500,000,000 for the fiscal year ending June 30, 1973; [and] $600,000,000 for the fiscal year ending June 30, 1974*; $750,000,000 for the fiscal year ending June 30, 1975; $830,000,000 for the fiscal year ending June 30, 1976; and $985,000,000 for the fiscal year ending June 30, 1977.*

### *AVAILABILITY OF APPROPRIATIONS*

*Sec. 410D. Notwithstanding any other provision of law, unless enacted after the date of enactment of this section expressly in limitation of the provisions of this section, funds appropriated for any fiscal year to carry out any program for which appropriations are authorized by the Public Health Service Act (42 U.S.C. 201) or the Mental Retardation Facilities and Community Mental Health Centers Construction Act of 1963 (42 U.S.C. 2661) shall remain available for obligation and expenditure until the end of such fiscal year.*

* * * * * * *

## PART G—ADMINISTRATIVE PROVISIONS

### DIRECTORS OF INSTITUTES

[Sec. 454. The Director of the National Institutes of Health and the Director of the National Cancer Institute shall be appointed by the President. Except as provided in section 407(b)(9), the Director of the National Cancer Institute shall report directly to the Director of the National Institutes of Health.]

*Sec. 454. (a) The Director of the National Institutes of Health shall be appointed by the President by and with the advice and consent of the Senate. Appointees shall be eligible for reappointment.*

*(b) The Director of the National Cancer Institute shall be appointed by the President. Except as provided in section 407(b)(9), the Director of the National Cancer Institute shall report directly to the Director of the National Institutes of Health.*

*Sec. 455. (a) There is established the President's Biomedical Research Panel (hereinafter in this section referred to as the 'Panel') which shall be composed of (1) the Chairman of the President's Cancer Panel; and (2) four members appointed by the President, who by* *virtue of their training, experience, and background are exceptionally qualified to appraise the biomedical research program of the National Institutes of Health (including the research program of the National Institute of Mental Health). At least three of the members of the Panel shall be distinguished scientists or physicians.*

*(b)(1) Appointed members of the Panel who are appointed pursuant to clause (2) of subsection (a), shall be appointed for three-year terms, except that (i) in the case of the four members first appointed after the date on which this section becomes effective, two shall be appointed for a term of one year and two shall be appointed for a term of two years, as designated by the President at the time of appointment, and (ii) any member appointed to fill a vacancy occurring prior to the expiration of the term for which his predecessor was appointed shall be appointed only for the remainder of such term.*

*(2) The President shall designate one of the appointed members to serve as Chairman of the Panel for a term of one year.*

*(c) Appointed members of the Panel shall each be entitled to receive the daily equivalent of the annual rate of basic pay in effect for grade GS–18 of the General Schedule for each day (including traveltime) during which they are engaged in the actual performance of duties vested in the Panel, and shall be allowed travel expenses (including a per diem allowance) under section 5703(b) of title 5, United States Code.*

*(d) The Panel shall meet at the call of the Chairman, but not less often than twelve times a year. A transcript shall be kept of the proceedings of each meeting of the Panel, and the Chairman shall make such transcript available to the public.*

*(e) The Panel shall monitor the development and execution of the biomedical research programs of the National Institutes of Health (including the research program of the National Institute of Mental Health) under this section, and shall report directly to the President. Any delays or blockages in rapid execution of the biomedical research programs of the National Institutes of Health (including the research program of the National Institute of Mental Health) shall immediately be brounght to the attention of the President and the Senate Committee on Labor and Public Welfare, the House Committee on Interstate and Foreign Commerce, the Senate Committee on Appropriations and the House Committee on Appropriations. The Panel shall submit to the President periodic progress reports on the biomedical research programs of the National Institutes of Health (including the research program of the National Institute of Mental Health) and annually a evaluation of the efficacy of the biomedical research programs of the National Institutes of Health (including the research program of the National Institute of Mental Health) and suggestions for improvements, and shall submit such other reports as the President shall direct. At the request of the President, it shall submit for his consideration a list of names of persons for consideration for appointment as Director of the National Institutes of Health.*

## IX Appendix

The following are communications which the Committee has received thus far in respect to the President's Biomedical Research Panel. All but one endorses the need for such a Panel.

American Dental Association,
*Washington, D.C., March 5, 1974.*

Hon. Edward M. Kennedy,
*Chairman, Subcommittee on Health, Committee on Labor and Public Welfare, U.S. Senate, Washington, D.C.*

Dear Senator Kennedy: The American Dental Association is pleased to have this opportunity to present its views on S. 3023. The sponsors of this bill are to be commended for their efforts to strengthen the research programs of the National Institutes of Health.

In recent years, an increased emphasis on certain areas of research such as cancer and heart disease has created a competitive climate in which other important research activities have suffered. In the case of dentistry, the National Institutes of Dental Research is the third oldest of the research institutes, yet it is still one of the smallest of any of the N.I.H. basic research components. The outstanding contributions made by this Institute, and the international recognition it has achieved, is in large measure the product of its dedicated scientists and administrators.

The American Dental Association is deeply concerned that ill-judged actions to economize in some research areas in order to accelerate the progress of other, more visible, research programs will exact a heavy payment on our future research efforts. For this reason, the Association endorses the concept of a Biomedical Research Panel to monitor the "development and execution" of all the biomedical research programs of the National Institutes of Health.

It is recommended, however, that in addition to the Chairman of the President's Cancer Panel, the membership of the Biomedical Research Panel be increased to a minimum of four other members. This would permit the appointment of a broader and more representative cross-section of the scientific community. In keeping with this, it is also recommended that membership on the panel be determined on the basis of scientific achievement in the health field. To accomplish this, line 7 on page 2 of the bill should be amended to read "of the panel shall be distinguished health scientists."

The American Dental Association will greatly appreciate your consideration of these comments and respectfully requests the inclusion of this letter in the hearing record.

Sincerely,

Paul W. Kunkel,
*Chairman, Council on Legislation.*

[TELEGRAMS]

BALTIMORE, MD.

Senator EDWARD KENNEDY,
*Russell Senate Office Building,*
*Capitol Hill, D.C.:*

The American Gastroenterological Association urges you to support the new proposal for a Presidential Bio-Medical Research Panel. The emphasis on cancer research in the past, although desirable, has been at the expense of general support of NIH and all other biomedical research.

ALBERT I. MENDELOFF, M.D.,
*President, American Gastro Association.*

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NEW YORK, N.Y.

Senator EDWARD M. KENNEDY,
*Capitol Hill, D.C.:*

The American Heart Association supports the basic purpose of S. 3023, to establish a Presidential Biomedical Research Panel. There is a critical need for overview of the biomedical research program of the National Institutes of Health. While we are convinced of the necessity for increased Federal funding for cardio vascular research, we believe that this should not be accomplished at the expense of funding for other meritorious research projects.

To achieve the purpose of the legislation, however, it is absolutely essential that the panel be completely impartial. In addition, we in biomedical research hope that a mechanism can be found so that persons with the highest qualifications in the scientific community are appointed. We believe it would be unwise to impose any other specific conditions on membership.

RICHARD S. ROSS, M.D.,
*President, American Heart Association.*

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AMERICAN NURSES' ASSOCIATION,
*Kansas City, Mo., March 5, 1974.*

Hon. EDWARD M. KENNEDY,
*Chairman, Senate Subcommittee on Health, Committee on Labor and Public Relations, New Senate Office Building, Washington, D.C.*

DEAR SENATOR KENNEDY: The American Nurses' Association would like to express its support for provisions of S. 2893 to extend the National Cancer Act for three additional years.

It is imperative that this law be extended. Failure to do so would retard continued progress in the war on cancer and dissipate some of the potential benefits of knowledge already gained. Despite advances made in the treatment and management of this disease, great numbers of people still are affected. It continues to be one of the major causes of death in this country.

Nurses are acutely aware of the impact of cancer on both victims and their families. We want to emphasize the importance not only of continued and intensified research, but of the early application of research findings to bring the benefits as quickly as possible to patients and to potential victims of the disease.

In the final analysis, the justification for any such program lies in the progress it achieves toward conquest and cure. As nurses, we are constantly made aware of the human suffering caused by the various types of cancer.

Federal support for cancer research should, of course, in no way minimize the importance of other research programs. There are other diseases afflicting large numbers of people which require maximum attention of the federal government. Support of cancer research should not be at the expense of support for needed research in other areas.

We ask that this letter be made a part of the record.

Sincerely yours,

ROSAMOND C. GABRIELSON, M.A., R.N.,
*President.*

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[MAILGRAM]

CHARLOTTESVILLE, VA.

Senator EDWARD KENNEDY,
*Senate Office Building,*
*Washington, D.C.:*

I think bill S. 3023 is an important step in assuring continued progress of national bio-medical research efforts.

K. R. CHRISPELL, MD.,
*Member Association for Academic Health Centers.*

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ASSOCIATION FOR ACADEMIC HEALTH CENTERS,
*Washington, D.C., February 28, 1974.*

Hon. EDWARD M. KENNEDY,
*Chairman, Senate Subcommittee on Health, Old Senate Office Building, Washington, D.C.*

DEAR SENATOR KENNEDY: On behalf of the members and Board of Directors of the Association for Academic Health Centers (AAHC), I wish to communicate to you the strong endorsement of our membership for passage of this bill S. 3023, the Biomedical Research Act of 1974. Inasmuch as this bill favors the establishment of a biomedical panel at the National Institutes of Health, similar to the Cancer Advisory Panel, we believe the integrity and creative productivity of research will be greatly enhanced by this measure.

To provide you with a better background of the nature of our support, I believe a brief description of our membership is in order. Membership in the Association is on an institutional basis. Only one person from each institution is qualified to participate in the AAHC. This person is the chief executive health officer of the institution with senior responsibility for *all* of the health educational programs of the institution.

In addition to the above membership category, persons responsible for state-wide systems of health education are also members. We have representation from 84 health sciences centers (an institution with a school of medicine, a teaching hospital and at least one other health school) in the United States.

The objective of the AAHC is to represent nationally the collective efforts of higher education devoted to producing the knowledge and skills necessary to meet the health needs of the people. Within this framework of commitment, we believe the establishment of a President's Biomedical Research Panel is most appropriate and essential to the continuing progress of national biomedical research efforts.

With best regards.

Sincerely yours,

EDMUND D. PELLEGRINO, M.D.,
*President, AAHC,*
*Chancellor, University of Tennessee Medical Units.*

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ASSOCIATION OF AMERICAN MEDICAL COLLEGES,
*Washington, D.C., March 1, 1974.*

Hon. EDWARD M. KENNEDY,
*Chairman, Subcommittee on Health, Senate Labor and Public Welfare Committee, Washington, D.C.*

DEAR MR. CHAIRMAN: The Association of American Medical Colleges supports the intent of legislation you recently introduced to establish a Presidential Biomedical Research Panel to monitor the progress of all National Institutes of Health and National Institutes of Mental Health research programs.

The Nation's biomedical research scientists have been disturbed by recent appointments to the NIH and NIMH Councils. In order to ensure that the Presidential Biomedical Research Panel is composed of individuals of stature, respected by the scientific community, we suggest the following changes to strengthen this legislation.

1. Appointment to the panel should be subject to the advice and consent of the Senate.
2. The legislation should require the President to solicit recommendations from the National Academy of Sciences for individuals to serve on this panel. This mechanism would ensure that the three scientific members of the panel will be individuals of stature within the scientific community.
3. The Association recommends that the activities of this panel should be subject to review by the Congress three years following enactment of the legislation.

The Association appreciates the opportunity to comment on this legislation.

Sincerely yours,

JOHN A. D. COOPER, M.D.

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THE ASSOCIATION OF STATE
AND TERRITORIAL HEALTH OFFICIALS,
*Washington, D.C., February 6, 1974.*

Hon. EDWARD M. KENNEDY,
*Chairman, Subcommittee on Health, Committee on Labor and Public Welfare, U.S. Senate, Washington, D.C.*

DEAR MR. CHAIRMAN: I am writing on behalf of the Association of State and Territorial Health Officials to express support for the enactment of the National Cancer Act of 1974, S. 2893, that you introduced on January 24, 1974.

This Association strongly endorses the increases proposed under section 5 of the bill that would increase the authorizations for appropriations for cancer control programs to $50 million in 1975, $65 million in 1976 and $85 million in 1977. Such funds are essential to our national effort to reduce the toll of cancer through prevention and early detection programs.

Let me take this opportunity to commend the National Cancer Institute for its effective leadership in the implementation of cancer control programs as authorized by the National Cancer Act. This Association is working very closely with the Institute in this endeavor.

With kindest regards, I am

Sincerely,

MAURICE S. REIZEN, M.D., *President.*

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[TELEGRAM]

HOUSTON, TEX.

Senator TED KENNEDY,
*Capitol Hill, D.C.:*

S. 3024 is a very important step to assure continued progress in national biomedical research efforts I urge its adoption.

JOE MERRILL,
*Executive Vice-President Baylor College of Medicine.*

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[MAILGRAM]

BOSTON, MASS.

Senator EDWARD KENNEDY,
*Capitol Hill,*
*Washington, D.C.:*

I support your bill, the Biomedical Research Act of 1974, because it is important to the continued progress of national biomedical research efforts.

RICHARD H. EGDAHL,
*Director Boston University Medical Center.*

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COLLEGE OF PHYSICIANS AND SURGEONS
OF COLUMBIA UNIVERSITY,
*New York, N.Y., March 1, 1974.*

Hon. EDWARD M. KENNEDY,
*Senate Office Building,*
*Washington, D.C.*

DEAR SENATOR KENNEDY: I am writing to support S. 3023 to establish a Bio-medical Research panel. Currently there is a lack of communication between the Executive Branch and the Bio-medical Research area.

Your bill will go a long way in establishing such communications.

Sincerely,

LOWELL M. GREENBAUM, Ph.D., *Professor.*

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Cornell University,
*Ithaca, N.Y., March 7, 1974.*

Senator Edward M. Kennedy,
*Senate Office Building,*
*Washington, D.C.*

Dear Senator Kennedy: I am writing to urge passage of bill S. 3023 which your committee has introduced to establish a President's Bioresearch Panel. As proposed, this panel would include the chairman of the President's Cancer Panel, and two additional members who are distinguished scientists or physicians. They would monitor developments and execution of biomedical research programs of NIH and report directly to the President. Such a panel is essential for preventing delays or blockades in execution of biomedical programs of NIH which need to be brought to the attention of the President and the Senate Labor and Public Welfare and House Interstate and Foreign Commerce Committees. Essential research programs in health must have assurance of continuous support and immediate action from the administration. The bill is an excellent idea and one we have needed for a long time.

Sincerely yours,

Willard J. Visek, Ph.D., M.D.,
*Professor of Nutrition and Comparative Metabolism.*

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[MAILGRAM]

Durham, N.C.

Senator Edward Kennedy,
*Capitol Hill, D.C.:*

We support the new amendment to the cancer bill, specifically we believe that a national presidential Biomedical Research Panel is necessary to provide emphasis on the many important areas of Biomedical research. Although the recent emphasis on cancer research was necessary, we should recognize the need for a similar thrust in other areas of biomedical research which have an equal import to the Nation's health.

Dr. M. P. Tyorchief,
*Gastroenterology Department of Medicine Duke University.*

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[TELEGRAMS]

New York, N.Y.

Senator Edward Kennedy,
*Capitol Hill, D.C.:*

Dear Senator Kennedy: Committee on National Medical Policy of the American Society for Clinical Investigation, wholeheartedly endorses S. 3023 providing for a President's Biomedical Research Panel. We deeply appreciate your supportive comments and constructive action.

Neal S. Bricker M.D.,
*Chairman, Albert Einstein College of Medicine.*

Bronx, N.Y.

Senator Edward M. Kennedy,
*Old Senate Office Building,*
*Washington, D.C.:*

I would like to urge you to support S. 3023 to establish a Presidential Biomedical Research Panel. Such a prestigious group would serve to insure the continued growth and development of American biomedical research and training in all areas for the future benefits of mankind.

Ernst R. Jaffe, M.D.,
*Acting Dean, Albert Einstein College of Medicine.*

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Philadelphia, Pa.

Hon. Edward Kennedy,
*Senator of Commonwealth of Massachusetts, Senate Office Building,*
*Washington, D.C.:*

The Board of Trustees and Administration of Hahnemann Medical College and Hospital unanimously endorses your proposed Bio-Medical Research Act of 1974 (S. 3023) calling for the establishments of a President Bio-Medical Research Panel, similar to the Cancer Advisory Panel. We believe this bill will assure continued progress and integrity of America's bio-medical efforts in research.

Wharton Shober,
*President and Chief Executive Officer,*
*Hahnemann Medical College and Hospital.*

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Philadelphia, Pa.

Senator Edward Kennedy,
*Capitol Hill, D.C.:*

The proposed biomedical research bill is of extreme importance to the advancement of medicine in the U.S. I give it my full support.

Peter A. Herbut, M.D.,
*President, Thomas Jefferson University.*

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[MAILGRAM]

Philadelphia, Pa.

Senator Edward Kennedy,
*Senate Office Building,*
*Washington, D.C.:*

Biomedical Research Act 1974 (S. 3023) important step in assuring viability and continued progress in U.S. biomedical research.

Thomas W. Langfitt M.D.,
*Acting Vice President for Health Affairs.*

LOMA LINDA UNIVERSITY,
*Loma Linda, Calif., March 5, 1974.*

Hon. EDWARD M. KENNEDY,
*U.S. Senate,*
*Washington, D.C.*

DEAR SIR: It has come to my attention that you have introduced a bill (S. 3023) to establish a Presidential Biomedical Research Panel in an endeavour to strengthen the program of the National Institutes of Health. May I indicate the support of our faculty here in this department of Loma Linda University for this bill and encourage you in your efforts to improve the support for the NIH programs.

As you are well aware, the NIH budget in recent years has been inadequate to fund many valuable research projects under way in the medical schools and other research institutions of this country. In our own department, funds for significant research in areas such as the safety of new carbamate pesticides, the problem of drug-induced anemia and the effects of chronic methadone administration on the physiology of the brain have been severely cut or eliminated even when approved by the NIH advisory committees. Congressional action to alleviate this unfortunate situation is most urgently needed.

Your concern for and interest in these problems is much appreciated.

Sincerely yours,

IAN M. FRASER, Ph. D.
*Chairman and Professor.*

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LOMA LINDA UNIVERSITY,
*Loma Linda, Calif., March 1, 1974.*

Senator EDWARD M. KENNEDY,
*U.S. Senate,*
*Washington, D.C.*

DEAR SENATOR KENNEDY: I am writing to support your bill S. 3023 to establish a Presidential Biomedical Research Panel.

I am also urging my State Senators, Alan Cranston and John V. Tunney to support your bill.

Thank you.

Sincerely yours,

LAWRENCE D. LONGO, M.D.

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LOMA LINDA UNIVERSITY,
*Loma Linda, Calif., March 6, 1974.*

Senator EDWARD M. KENNEDY,
*Senate Office Building,*
*Washington, D.C.*

DEAR SENATOR KENNEDY: As a biomedical scientist and cancer researcher, I am extremely concerned about some of the changes in the approaches to solving the cancer problem which have taken place recently. The cancer problem is not an engineering problem, and therefore cannot be approached successfully with the same methods used to put man on the moon. To limit funds for cancer research to a few large institutions seems, to me, to be very short-sighted.

Bill S. 3023 establishing a Presidential Biomedical Research Panel has recently come to my attention. I want to go on record as supporting this bill. It should expedite the execution of biomedical research programs of the NIH. It would seem advisable to have five rather than three panel members.

Thank you for your interest in helping to find a solution to the cancer problem.

Sincerely,

ROBERT L. NUTTER, Ph.D., *Professor.*

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[TELEGRAMS]

TOLEDO, OHIO.

Senator TED KENNEDY,
*Capitol Hill, D.C.:*

S. 3023 represents an important move towards establishing integrity and continued medical research.

M. C. ANDERSON, M.D.
*President Medical College of Ohio.*

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NASHVILLE, TENN.

Senator EDWARD KENNEDY,
*Capitol Hill, D.C.:*

This telegram is sent to you in my support for your amendment to the national cancer bill (S. 3023) which I understand will come up for vote soon. I totally endorse it as well as many other persons in this academic and scientific community.

EDWARD G. HIGH,
*Professor and Chairman,*
*Mehrry Medical College.*

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RICHMOND, VA.

Senator EDWARD KENNEDY,
*Senate Office Building,*
*Capitol Hill, D.C.:*

I think your Biomedical Research Act of 1974 (S. 3023) is an important step in assuring integrity and continued progress of national biomedical efforts.

M. PINSON NEAL, Jr., M.D.,
*Medical College of Virginia.*

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WASHINGTON, D.C.

Senator EDWARD M. KENNEDY,
*Capitol Hill, D.C.:*

As former associate director for clinical care at NIH I greatly appreciate the importance of program balance at NIH and urge you agree to amendment to Cancer Act which provides for a President's biomedical research panel.

THOMAS CHALMER, M.D.
*President, Mount Sinai Medical Center, New York City.*

NEW YORK, N.Y.

Hon. EDWARD KENNEDY,
*Labor and Public Welfare Committee, Dirksen New Senate Office Building, Capitol Hill, D.C.:*

The National Hemophilia Foundation strongly supports the amendment to the Cancer Act which would provide for the creation of a Presidential Biomedical Research Panel while the President's Cancer Panel has been proven effective, it has created a distortion in funding at the National Institutes of Health. What is needed is a panel to determine the overall direction and priority for all of the institutes which will be provided for by this amendment.

ROY S. HEAVNER, *President.*

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NORTHWESTERN UNIVERSITY,
*Chicago, Ill., March 1, 1974.*

Senator EDWARD KENNEDY,
*U.S. Senate,*
*Washington, D.C.*

DEAR SENATOR KENNEDY: I wish to express my support for the amendment to the Cancer Bill sponsored by Senators Javits, Schweiker, Beall and yourself.

The appointment of a policy-making panel for The National Institutes of Health will give direction and stability to biomedical investigation in this country. Both of these characteristics have been sadly lacking of late.

Once again, may I express my enthusiastic support for this amendment.

Sincerely yours,

MURRAY L. LEVIN, M.D.,
*Associate Professor of Medicine.*

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OAK RIDGE NATIONAL LABORATORY,
*Oak Ridge, Tenn., March 1, 1974.*

DEAR SENATOR KENNEDY: I and my colleagues support your move, with Senator Schweiker, Javits, and Beall, to create a special panel to oversee the National Institutes of Health. Whether this remains as S-3023 or is attached to another bill is immaterial.

I am informing my two Senators, Howard Baker and Bill Brock, of my interest (and that of essentially every scientists here) and am urging their support of the bill.

Sincerely,

WALDO E. COHN,
*Senior biochemist, Biology Division.*

ROCHE INSTITUTE OF MOLECULAR BIOLOGY,
*Nutley, N.J., March 6, 1974.*

Senator EDWARD KENNEDY,
*U.S. Senate,*
*Washington, D.C.*

DEAR SENATOR KENNEDY: I am writing to indicate my support of your bill (S3023) to establish a Biomedical Research panel. This bill should do much to shorten the lag between scientific discovery and application to human medical care.

Yours sincerely,

B. L. HORECKER, *Professor.*

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[TELEGRAM]

BOYNTON BEACH, FLA.

Senator EDWARD M. KENNEDY,
*Capitol Hill, D.C.:*

Although I favor stronger support for many areas of basic biomedical research and will for the reasons set forth in my testimony do all in my power to obtain such support, I have very serious reservations about the proposed legislation which would create a President's Biomedical Research Panel for the following reasons:

1. The Cancer Panel is a very unusual and unorthodox organizational arrangement that will only work effectively if it is reserved for unusual circumstances of extraordinary and specific priority as cancer research was felt to be. The Secretary of HEW could not be expected to accept this organizational anomaly for substantially increased areas of his basic responsibility;

2. The Cancer Panel has been an effective tool because the President has genuinely shared the priority it was designed to implement and the President has made his support of the Panel clear to all concerned. As an instrument to proposed the President's priorities the Panel would not in my opinion be effective. The Panel could easily be rendered ineffective without the President's strong and well publicized support;

3. By trying to extend the special emphasis that the Panel has helped to achieve for cancer to all areas of biomedical research we are more likely to lose the cancer priority to gain the same priority for a vastly extended area;

4. The effective discharge of the duties as Chairman of the President's Cancer Panel requires a very substantial portion of the time of the occupants of that position. The added duties envisaged by the proposed bill would make this a full-time job. Such a full-time person attempting to function outside the regular organizational set-up would be likely to become a nuisance who would soon lose his effectiveness;

5. In my opinion there is a better prospect of achieving the desired ends with the present set-up and a much better chance of continuing a vital and effective cancer program;

6. I made these views known to Lee Goldman and Jay Cutler before my departure. I assumed they will come as no surprise to you;

7. I am highly hopeful that with a little more time we can obtain the desired priorities with respect to other biomedical research with the present organization without risking the loss of the momentum in the cancer program by changing the set-up in mid-stream. I hope these views will be helpful in your deliberations.

Warm regards,

BENNO SCHMIDT.

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SCRIPPS CLINIC AND RESEARCH FOUNDATION,
*La Jolla, Calif., March 6, 1974.*

Senator EDWARD M. KENNEDY,
*U.S. Senate,*
*Washington, D.C.*

DEAR SENATOR KENNEDY: The establishment of a Presidential Biomedical Panel (S. 3023) deserves considerable support. It is important to bring to the attention of the executive branch of the government solid information on the merits of biomedical research. Careful monitoring of the programs of the NIH will surely accomplish such a goal. Much of the painstaking efforts of the Congress to understand the benefits of research and the needs and problems currently facing the biomedical research community would hopefully through such a committee be transmitted to those in the administrative branch who are expert in methods of budget but not science. I would favor a panel consisting of five scientists rather than three, as is called for in the bill, which would be necessary to bring to the panel greater representation of so complex a body of information.

Sincerely,

CHARLES G. COCHRANE, M.D.

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[TELEGRAMS]

STANFORD, CALIF.

Hon. EDWARD M. KENNEDY,
*Old Senate Office Building,*
*Capitol Hill, D.C.:*

DEAR SENATOR KENNEDY: I support provisions of S-3023 for a biomedical research panel and for other measures in support of a vigorous biomedical research program for this Nation.

CLAYTON RICH, M.D.,
*Vice President for Medical Affairs,*
*Stanford University School of Medicine.*

ALBANY, N.Y.

Sen. EDWARD KENNEDY,
*Capitol Hill, D.C.:*

Regarding the Biomedical Act of 1974, I think this bill is an important step in assuring integrity and continued progress of national bio-medical research efforts.

THOMAS W. MOU, M.D.,
*Provost for the Health Science,*
*State University of New York.*

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PHILADELPHIA, PA.

Hon. EDWARD M. KENNEDY,
*Senate,*
*Capitol Hill, D.C.:*

Recent history underlines the importance of monitoring the execution of NIH research programs. The panel envisioned in your S–3023 would be an important step toward accomplishing that purpose.

PAUL TOKIN, M.D.,
*Vice President and Provost Health Sciences Center,*
*Temple University.*

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[MAILGRAM]

NEW ORLEANS, LA.

Senator EDWARD M. KENNEDY,
*Subcommittee on Health,*
*Washington, D.C.:*

Please pardon the terseness of this communication but I only learned of the urgency of the following today. I wish to lend strong support to your move (Bills HR 12314 and S2893) to provide for a panel of five non-Federal representatives from the scientific community to review priorities and foster implementation of monetary support for bio-medical projects under Federal purvey.

JOHN H. PHILLIPS, M.D.,
*Professor of Medicine, Tulane University.*

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[TELEGRAM]

BIRMINGHAM, ALA.

Senator EDWARD KENNEDY,
*Capitol Hill, D.C.:*

S–3023 establishing a Biomedical Research Panel would move toward continued effective national biomedical research. Urge support of this measure.

S. RICHARDSON HILL,
*Junior Md/University of Alabama.*

University of California,
Department of Molecular Biology and Biochemistry,
School of Biological Sciences,
*Irvine, Calif., March 6, 1974.*

Hon. Edward M. Kennedy,
*Senate Office Building,*
*Washington, D.C.*

Dear Senator Kennedy: I am writing to you with regard to the formation of a Presidential Biomedical Research Panel, whose purpose would be to monitor the development and execution of biomedical research programs of the National Institutes of Health.

I am writing to you to indicate my support for the formation of this committee. I feel that it will expedite the movement of funds appropriated by the Congress to the NIH. I also feel it will expedite the proposed research programs, and will allow a more direct communication line on matters of the budget from the NIH, through the committee, to the President on a different vein than perhaps the head of the NIH, who is a Presidential appointee who may favor Presidential programs. This committee, I feel, would provide a second voice, which would help prevent manipulation of the National Institutes of Health and our own health care programs for political reasons.

Sincerely yours,

G. A. Granger,
*Professor of Immunology and Microbiology.*

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University of California,
Scripps Institution of Oceanography,
*La Jolla, Calif., March 8, 1974.*

Senator Edward M. Kennedy,
*Senate Office Building,*
*Washington, D.C.*

Dear Senator Kennedy: I am writing in appreciation of your efforts with regard to the introduction of Bill S3023, along with Senators Beall, Javits, and Schweiker, to establish a Presidential Biomedical Research Panel. For some time we in the biomedical research community have been concerned about the disproportionate influence exercised by the Executive, as compared with the Legislative, branch on Federal biomedical research programs. The Executive influence is wielded chiefly through the Office of Management and Budget, an agency with little if any of the scientific expertise needed to evaluate the programs over which it holds such power. Creation of a Biomedical Research Panel, as embodied in your bill, will ensure that informed scientific input is received both by the President and by appropriate Congressional committees. Although I would prefer to see a panel of five members, rather than the three mentioned in your bill, I very much hope that S3023 will pass and be implemented.

By copy of this letter I am conveying my sentiments to your cosponsors and to my own Senators.

Yours sincerely,

Christopher K. Mathews,
*Visiting Professor.*

[MAILGRAM]

UNIVERSITY OF COLORADO MEDICAL CENTER,
*Denver, Colo.*

Senator EDWARD KENNEDY,
*Senate Office Building,*
*Washington, D.C.:*

Senate bill 3023 has strong support from the faculty and administration of the University of Colorado Medical Center, having served as the first director of the National Institute of Child Health and Human Development during your late brother's administration I have viewed with grave pain the decline of the National Biomedical effort. It is time to reestablish a strong bipartisan biomedical research policy.

Your bill can do this.

With best wishes for success,

ROBERT A. ALDRICH, M.D.,
*Vice President for Health Affairs.*

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UNIVERSITY OF COLORADO MEDICAL CENTER,
*Denver, Colo.*

Senator EDWARD KENNEDY,
*Senate Office Building,*
*Washington, D.C.:*

We support the proposed amendment to the Cancer Act which would provide for the President's Biomedical Research Panel. The cancer program has expanded greatly as a result of the Concer Act but as a biomedical researcher we are concerned that this progress have been at the expense of other research programs. We need such a panel to provide a balanced view of the research needs and opportunities available to the NIH.

F. KERN, Jr., M.D.
F. SIMON, M.D.,
H. CLAMAN, M.D.,
V. OSTROWER, M.D.
W. BROWN, M.D.

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UNIVERSITY OF SOUTHERN CALIFORNIA,
*Los Angeles,, Calif., March 8, 1974.*

Hon. EDWARD M. KENNEDY,
*United States Senate,*
*Washington, D.C.*

MY DEAR SENATOR KENNEDY: This letter is in support of your Bill S. 3023 to establish a Presidential Biomedical Research Panel. The development and execution of biomedical research programs have been substantially arrested. This stems, in part, from the low priority assigned to this human enterprise by the present administration. We believe it essential that the influence of the Office of Management and

Budget be counterbalanced by a panel of the type provided for in your bill.

Sincerely yours,

MAX HARRY WEIL, M.D.,
*Director and Clinical Professor,*
*Medicine and Biomedical Engineering.*

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[TELEGRAM]

UNIVERSITY OF FLORIDA,
*Gainesville, Fla.*

Senator EDWARD M. KENNEDY,
*Capitol Hill,*
*Washington, D.C.:*

Continued effort in biomedical research is necessary in the quest for treatment and cures. We support bill S. 3023 as an approach to progressive legislation for research.

EDMUND ACKELL,
*Vice-President for Health Affairs.*

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J. HILLIS MILLER HEALTH CENTER,
UNIVERSITY OF FLORIDA,
*Gainesville, Fla., March 6, 1974.*

Senator EDWARD M. KENNEDY,
*Chairman, Subcommittee on Health, Old Senate Office Building,*
*Washington, D.C.*

DEAR MR. KENNEDY: This letter is written in support of S. 3023 to establish a President's biomedical research panel. I think the scientific and health community is eager to best utilize funds made available to them for biomedical research. Every indication which we have received is that such a panel is needed and would expedite the efficient utilization of available funds.

Sincerely yours,

DON L. ALLEN, D.D.S., M.S.,
*Interim Dean.*

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DIVISION OF SPONSORED RESEARCH,
UNIVERSITY OF FLORIDA,
*Gainesville, Fla., February 28, 1974.*

Senator EDWARD M. KENNEDY,
*Chairman, Subcommittee on Health, Old Senate Office Building,*
*Washington, D.C.*

DEAR SENATOR KENNEDY: One of the severest frustrations that has faced those of us attempting to develop answers to pressing health problems has been the constrant stream of road blocks to biomedical research stemming from OMB actions. I interpret these as reflecting Administration attitude since actions speak louder than words.

The introduction of S. 3023 by Senators Kennedy, Beall, Javits, and Schweiker to provide a mechanism for monitoring the development and execution of biomedical research programs provides a way to develop a rational approach to the problem of maintaining factual input for presidential and congressional decisions. The present, almost capricious decision-making with regard to biomedical research could then be ended or exposed for what it is.

Your efforts in introducing and supporting this action are welcomed and appreciated.

Sincerely yours,

George K. Davis,
*Director, Division of Sponsored Research.*

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C. V. Whitney Laboratory,
University of Florida,
*St. Augustine, Fla., March 7, 1974.*

Senator Edward M. Kennedy,
*Chairman, Subcommittee on Health, Old Senate Office Building, Washington, D.C.*

Dear Senator Kennedy: This is to express my support for S. 3023 which you have introduced. American biomedical science leads the world, and it would be a dreadful step backward if our forward thrust were to be blunted. Even though the advances in biomedical science have been spectacular over the past 20 years, it is only the tip of the iceberg that has been revealed. A number of quantum jumps in our knowledge of living processes are discernable—for example membrane phenomena, the three-dimensional structure and activity of huge macromolecules, neurobiological advances and their significance for understanding cell and organ behavior. We need this kind of information for better understanding of human disease.

I hope your efforts will be successful, for it will be tragic if support for fundamental research falters as it has been doing for the past few years.

Sincerely,

Samuel Gurin,
*Director, Professor of Biochemistry.*

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J. Hillis Miller Health Center,
University of Florida,
*Gainesville, Fla., March 1, 1974.*

Hon. Edward M. Kennedy,
*Chairman, Subcommittee on Health, Old Senate Office Building, Washington, D.C.*

Dear Senator Kennedy: This is to applaud your introduction of S. 3023, and to express the wholehearted support of our faculty and administration for this bill. It would do much to insure the orderely implementation of legislative intent, with respect to biomedical research programs of the NIH. Naturally, it is the extramural portion of the NIH program that concerns us most, and I know that you are fully aware of the distressing cutbacks, slowdowns and phase-outs in research and research training programs in our medical schools that have been occasioned by impoundment and other administrative delaying tactics in recent years. Such delays can only be detrimental to the public health, as they postpone development of new knowledge necessary to control or prevent disease.

We strongly urge passage of the bill, and express our thanks to you for your initiative in this matter.

Sincerely yours,

CHANDLER A. SETSON, M.D., *Dean.*

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UNIVERSITY OF ILLINOIS,
*Urbana-Champaign, March 1, 1974.*

To: Senators Kennedy, Beall, Javits and Schweiker.

From: F. A. Kummerow, Director, The Burnsides Research Laboratory.

Subject: Senate Bill S–3023. The Establishment of a President's Biomedical Research Panel.

I would like to express my support for S–3023. The research community is dedicated to the solution of health problems in the U.S.A. However, it cannot operate in a vacuum. I know from my own participation in volunteer health organizations, such as the Illinois Heart Association, that the general public understands the need for a continued and steady funding of research programs. This understanding at the grass roots level will support carefully thought-out decisions at the national level. The Office of the President needs the support that a distinguished panel of scientists can provide. The present dependence on the Office of Management and Budget for such guidance has not provided for an optimum research effort. S–3023 will be of benefit to the Congress, the Office of the President and the scientific community. We must all work in harmony in order to provide for maximum value from the funds that are provided for research programs.

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UNIVERSITY OF KENTUCKY,
*Lexington, Ky., February 28, 1974.*

Senator EDWARD M. KENNEDY,
*U.S. Senate,*
*Washington, D.C.*

DEAR SENATOR KENNEDY: I am writing in behalf of the Public Affairs Committee of the Federation of American Societies for Experimental Biology (FASEB) to support Senate Bill S. 3023. It has been apparent for a number of years that one of the impediments to the efficient use of the federal dollar in biomedical research has been poor communication among the administration, certain key Congressional committees, and the NIH. Objectives and motives are sometimes misunderstood, and, in the resulting confusion, time and money are wasted. The proposed President's Biomedical Research Panel would serve as a high-level coordinating body that would substantially reduce these kinds of waste. I therefore strongly endorse your efforts in behalf of S. 3023.

Sincerely,

Henry R. Hirsch,
*Associate Professor.*

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[TELEGRAM]

Worcester, Mass.

Senator Edward Kennedy,
*Capitol Hill D.C.:*

I urge your support of Senate bill Number 3023 at the subcommittee on health meeting on March 6th. The need for a President of Biomedical Research Panel and continuing support of basic research is clear and urgent. This will have direct effects on the health of the Nation.

R. W. Butcher, Ph. D.,
*University of Massachusetts Medical School.*

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University of Miami,
*Miami, Fla., February 28, 1974.*

Senator Edward Kennedy,
*Subcommittee on Health,*
*Dirksen Senate Office Building,*
*Washington, D.C.*

Dear Senator Kennedy: As a member of the American Federation for Clinical Research and a councillor of its Southern subsection, I urge your support of the current cancer legislation. Academicians consider passage of this bill which provides for independent scientific control immune from Federal (Presidential) influence for fund distribution as critical.

Thank you very much.

Sincerely,

Gerald S. Levey, M.D.,
*Professor of Medicine.*

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[TELEGRAMS]

Chapel Hill, N.C.

Senator Edward Kennedy,
*Capitol Hill D.C.:*

Senate 3025 constitutes an important forward step to protect and support national biomedical research efforts. I only hope it could be even stronger.

Cecil G. Sheps, M.D.,
*Vice Chancellor, Health Science,*
*University of North Carolina.*

PITTSBURGH, PA.

Hon. EDWARD KENNEDY,
*U.S. Senate, Senate Office Building,*
*Washington, D.C.:*

I support your statesmanlike efforts to establish a President's Biomedical Research Panel which would provide real leadership for the Nation's biomedical research efforts.

F. S. CHEEVER,
*Vice Chancellor Health Professions,*
*University of Pittsburgh.*

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DALLAS, TEX.

Hon. EDWARD KENNEDY,
*U.S. Senate,*
*Washington, D.C.:*

Your bill entitled Biomedical Research Act of 1974 is vitally important to the preservation of a vigorous national biomedical research effort. Such a national effort is absolutely essential if this country is going to continue as a world leader in the health field.

CHARLES C. SPRAGUE, M.D.,
*President, The University of Texas Health Science Center at Dallas.*

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THE UNIVERSITY OF TEXAS MEDICAL BRANCH,
*Galveston, Tex.*

DEAR SIR: I was just informed about bill S. 3023 and I want you to know that I consider this of extreme importance for the continuation of biomedical research. This is exactly what is needed and what is of utmost urgency now so many good projects get approved but not funded. My own project was for instance approved last November with an excellent critique but it has not been funded yet. In the mean time research was reduced due to the loss of technical help. My own future is in jeopardy since also my salary is paid from this grant. We do not know anymore where we stand due to these delays in funding. Action is indeed necessary.

Sincerely yours,

LUDDO B. NANNINGA,
*Research Professor,*
*Department of Physiology and Biophysics.*

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[TELEGRAMS]

SYRACUSE N.Y.

Senator EDWARD M. KENNEDY,
*Capitol Hill D.C.:*

I support the Biomedical Research Act of 1974 (S–3023) as a means of strengthening integrity and further accomplishment in biomedical research.

LEWIS W. BLUEMLE, JR., M.D.,
*President, Upstate Medical Center.*

NASHVILLE TENN.

Senator EDWARD M. KENNEDY,
*Capitol Hill D.C.:*

I strongly support the national cancer bill S. 3023.

DR. ALLAN D. BASS,
*Professor of Pharmacology, Vanderbilt Medical School.*

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NASHVILLE TENN.

Senator EDWARD M. KENNEDY,
*Capitol Hill D.C.:*

I firmly urge the passage of an amendment to the NCB S. 3023 to include the appointment of a Biomedical Review Panel to monitor this bill.

HARRY P. BROQUIST,
*Professor Biochemistry, Vanderbilt University.*

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VANDERBILT UNIVERSITY,
*Nashville, Tenn., March 1, 1974.*

Hon. EDWARD M. KENNEDY,
*Subcommittee on Health, U.S. Senate, New Dirksen Senate Office Building, Washington, D.C.*

DEAR SENATOR KENNEDY: I am writing to indicate the importance I attach to the amendment I understand you plan to introduce on the Senate floor next week to the Bill to Extend and Amend The National Cancer Act of 1971 (S. 3023). The amendment, as I understand it, will create a panel of several individuals, drawn in large part from the scientific community, to review and oversee the overall funding of health science programs of the N.C.I., N.I.H., and N.I.M.H. This panel would report to both the President and the Congress and would be charged with maintaining balance and scientific diversity among the various programs. It would, therefore, be in a position to modulate significantly the increasing effort of the Executive Branch to politicize science. I want to commend you for introducing this legislation and to encourage you and your fellow Senators to resist what I suspect are strong efforts by the White House to defeat it on the Senate floor. I have talked to Mr. Dalrimple on Congressman Paul Rogers' staff, and he indicated that there would be little chance of further modifying their bill (H.R. 13053) in the full committee, but that he felt that, should your amendment pass, there would be little difficulty in incorporating it in conference.

Let me offer my appreciation for your continuing efforts on behalf of biomedical science and the health professions, and my best regards.

Sincerely,

DAVID N. ORTH, M.D.,
*Director, Cancer Research Center.*

[TELEGRAM]

NASHVILLE, TENN.

Senator EDWARD KENNEDY,
*Capitol Hill, D.C.:*

Strongly support your amendment to national cancer bill S. 3023, to establish Biomedical Research Panel to report to Congress and the President on NIH funding.

Dr. OSCAR TOUSTER,
*Professor and Chairman,*
*Department of Molecular Biology, Vanderbilt University.*

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UNIVERSITY OF WISCONSIN MEDICAL CENTER,
*Madison, Wis., February 27, 1974.*

Hon. EDWARD M. KENNEDY,
*U.S. Senate,*
*Washington, D.C.*

DEAR SENATOR KENNEDY: As a biomedical scientist who has been increasingly concerned about the fate of health research in the U.S.A., as well as in Latin America (see enclosed), I am most pleased to learn that you along with Senators Javits, Schweiker and Beall have introduced S. 3023, an amendment to the Public Health Service Act to strengthen the research programs on the National Institutes of Health. I have written to Senator Gaylord Nelson in this connection. Your amendment will be widely supported and applauded by the community of biomedical scientists as it represents a major step in insuring the integrity and renewed vigor of the National Institutes of Health which has been able until recently to foster an internationally renowned program of health research.

The partial separation of the Cancer Institute and the threats to further disintegration of the National Institutes of Health by the efforts to separate the Heart and Lung and Neurological Diseases Institutes have served to dishearten the biomedical community. Your amendment will go a considerable way in helping to reestablish the confidence of the biomedical scientists in the justifiable belief that their collective research efforts, if adequately supported, will contribute the basic knowledge, urgently needed for more effective diagnosis, treatment and prevention of not only cancer, and heart disease but also of arthritis, diabetes, and the many other ills of our citizens.

The enclosed report on Health Research in Latin America may be of interest to you. It reveals the difficulties which our sister nations in this hemisphere are facing in meeting their health research needs. The integrity and reinvigoration by more adequate financial support of the National Institutes of Health in their intra- and extramural research programs are essential not only to meet the needs and expectations of our own citizens, but also to serve as a model—and even as a source of support—for other countries, and in particular, Latin America.

Respectfully yours,

PHILIP P. COHEN,
*Professor of Physiological Chemistry.*

93d Congress } HOUSE OF REPRESENTATIVES { Report
*2d Session* } { No. 93-954

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# NATIONAL CANCER AMENDMENTS OF 1974

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March 27, 1974.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

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Mr. Staggers, from the Committee on Interstate and Foreign Commerce, submitted the following

## REPORT

[To accompany H.R. 13053]

The Committee on Interstate and Foreign Commerce, to whom was referred the bill (H.R. 13053) to amend the Public Health Service Act to improve the National Cancer Program and to authorize appropriations for such Program for the next three fiscal years, and for other purposes, having considered the same, report favorably thereon without amendment and recommend that the bill do pass.

### Summary of Legislation

H.R. 13053 as reported provides a three-year extension of the National Cancer Act with total authorizations for fiscal years 1975–77 of $2,565 million for the National Cancer Program and $200 million for cancer control programs. The legislation also makes the following substantive modifications in the National Cancer Act:

1. Specifies that the director of the National Cancer Institute (NCI) may make research and training grants without national advisory board review having direct costs of up to $35,000.
2. Requires the director of NCI to collect, analyze and disseminate information on nutrition programs for cancer patients and the relationship between nutrition and cancer.
3. Requires use of training stipends, fellowships, and career awards for training relevant to cancer.
4. Requires the director to submit, with the NCI's budget, estimates of the personnel needed for the cancer program.
5. Removes the limitation of fifteen on the number of cancer research and demonstration centers which the NCI may support.

6. Provides the director of NCI with additional authority to employ experts and consultants, make grants for construction, alteration and renovation of research facilities, and disseminate and interpret new information concerning cancer.

7. Mandates in law peer review throughout NIH of grant applications and contract projects in a manner comparable to that presently done administratively for grant applications, and

8. Extends permanently the present, expiring authority for the Secretary of HEW to contract for research projects.

## BACKGROUND

This proposed legislation provides new authority for the support of the National Cancer Program through a three-year extension of the National Cancer Act of 1971 (P.L. 92–218), and is a companion bill of S. 2893, introduced in the Senate by Mr. Kennedy on January 24, 1974. Hearings were held in the House on H.R. 12314, a bill similar to H.R. 13053, on February 5 and 6, 1974, and focused on the operation and effectiveness of the National Cancer Program; progress in cancer research; treatment and diagnostic methods made available to Americans since the passage of the National Cancer Act of 1971; new and improved techniques for delivering information to the biomedical community and to the public; how well the National Cancer Institute (NCI) organizational structure created by the 1971 Act has worked; and improvements which could be made in each of these areas. Almost all the testimony heard was supportive of the work accomplished by the National Cancer Program since the passage of P.L. 92–218 in December, 1971. In addition a Presidential message was introduced into the record reaffirming the President's commitment to a continued national effort against cancer. The legislation was considered by the Subcommittee on Public Health and Environment in open mark-up, introduced as a clean bill, H.R. 13053, and reported by unanimous voice vote. It was then considered by the Committee on Interstate and Foreign Commerce in open mark-up and reported by unanimous voice vote. It is cosponsored by the Chairman of the Committee and all members of the Subcommittee.

## COST OF LEGISLATION

As reported by the Committee, H.R. 13053 provides for authorizations of appropriations for three fiscal years for the National Cancer Program as shown in the following table.

TABLE 1.—NEW OBLIGATIONAL AUTHORITY FOR FISCAL YEARS 1975–77 UNDER H.R. 13053

[In millions of dollars]

| | Fiscal year— | | | |
|---|---|---|---|---|
| | 1975 | 1976 | 1977 | Total |
| National cancer program, sec. 410C of the Public Health Service Act | 750 | 830 | 985 | 2,565 |
| Cancer control program, sec. 409(6) of the Public Health Service Act | 50 | 65 | 85 | 200 |
| Total | 800 | 895 | 1,070 | 2,765 |

These authorizations may be compared to the following recent program budgetary experience.

TABLE 11.—RECENT BUDGET EXPERIENCE

TABLE 11.—RECENT BUDGET EXPERIENCE OF THE NATIONAL CANCER PROGRAM

[In millions of dollars]

| | Fiscal year— | | | | |
|---|---|---|---|---|---|
| | 1972 | 1973 | 1974 | 1975 | Total |
| National cancer program: | | | | | |
| Present obligational authority | 400.0 | 500.0 | 600.0 | | 1,500.0 |
| Appropriations | 379.0 | 462.2 | 555.1 | | 1,396.2 |
| Obligations | 378.0 | 425.7 | [1] 555.1 | | 1,358.8 |
| Budget requests | 372.2 | 428.2 | 466.0 | 555.0 | [2] 1,266.4 |
| Cancer control program: | | | | | |
| Present obligational authority | 2.0 | 30.0 | 40.0 | | 90.0 |
| Appropriations | 0 | 30.0 | 34.0 | | 64.0 |
| Obligations | 0 | 5.5 | 34.0 | | 39.5 |
| Budget requests | 0 | 4.0 | 34.0 | 45.1 | [2] 38.0 |

[1] Includes funds impounded in fiscal year 1973 and released in fiscal year 1974.

[2] Total does not include fiscal year 1975 request so that it is comparable to the totals above it.

## NEED FOR LEGISLATION

The National Cancer Program has progressed well since the passage of the National Cancer Act of 1971 and only a few changes are necessary to facilitate the full implementation of the Act. Cancer in its more than 100 forms constitutes one of the most devastating health problems of the American people. It is estimated that 655,000 Americans will develop cancer in 1974, and 355,000 will die. This makes cancer the second leading cause of death behind heart disease. Beyond an incalculable toll in suffering and family disruption, this disease produces an economic loss in the United States estimated at more than $15 billion annually. Yet the outlook is improving at a steadily accelerating pace. One out of every three persons who now have cancer can expect to be alive five years after treatment. There are one and a half million Americans who have had cancer but are now well. An additional one million cancer patients diagnosed and treated in the last 5 years are expected to live to join these ranks.

The National Cancer Act enlarged the authorities of the National Cancer Institute and the National Institutes of Health to conduct an expanded, intensified and coordinated National Cancer Program. This Program has two principal thrusts. The first is to speed the development of new knowledge by an intensive and coordinated research effort involving the broad scope of medical, biological, chemical and physical sciences. The second is to bring the most effective methods for the prevention and control of cancer to all the people of this nation through unprecedented demonstration and education efforts. This delivery of research results to the people uses the best of our present knowledge and will provide for the rapid application of new information as the National Cancer Program continues to gather momentum.

Even before the National Cancer Act was passed, investigators representing the U.S. scientific and medical community were brought together to begin planning a research strategy for the National Cancer

Program. The resulting plan, transmitted to the Congress by the President last year, sets forth research approaches needed for progress in the areas of cancer cause and prevention, detection and diagnosis, treatment, and rehabilitation.

It is not expected that a cure for cancer will be found in the space of a year or two—nor is it anticipated that there will even be a single cure for the many forms of cancer. Instead, scientists and physicians are exploring all promising avenues of research that may lead to identifying the causes of cancer, preventing cancer whenever possible, diagnosing cancer earlier and more accurately, and treating it more effectively. The host of individual advances all work toward the ultimate goal of preventing the occurrence of cancer, curing cancer when it does occur, and restoring former cancer patients to full and productive lives.

In 1971, the National Cancer Institute appropriation level was $233 million. In 1974, the appropriation level is $551 million, with an operating budget of $527,517,000. The Committee is in agreement with the Administration's emphasis on this program and their promise of future commitment.

Progress has been made in many areas. The international scientific community has been brought into the National Cancer Program, as called for by the Act, with research in 19 foreign countries being supported by the NCI. Further, the broad range of information programs envisioned by the Act have become operational to facilitate the exchange of scientific and medical information among scientists, physicians, other health professionals and the public.

The first thrust of the National Cancer Program is the development of new knowledge of cancer. As one facet of this the NCI has placed new emphasis on developing treatment methods that effectively use combinations of surgical, radiation, immunologic and drug therapy. In this area, the following examples illustrate the progress made under the auspices of the National Cancer Act of 1971:

> Half of those children with acute lymphocytic leukemia, a terrible cancer of the blood, now are alive five years after diagnosis when treated aggressively with radiation and a combination of anti-cancer drugs. Twenty years ago, this disease killed most of its victims within a few months and all of them within several years.
>
> Radiotherapy for the early stages of Hodgkin's disease, another cancer of the circulatory system, now produces five-year survival rates of more than 90 percent. This is compared to a 68 percent survivial rate for early Hodgkin's disease five years ago. A four-drug combination treatment for advanced Hodgkin's gives 65 percent survival after five years, a vast improvement over the survival rate of less than 10 percent five years ago.
>
> Patients with another form of lymphoma can achieve a five-year survival rate of 66 percent when this cancer is diagnosed early and treated with a combination of drugs. Five years ago, the rate was only about 20 percent.
>
> There are indications that breast cancer may yield eventually to a combination of drugs, surgery and radiation. Five-year survival rates for this disease, which kills more women than any other form of cancer, have remained near 60 percent for the past two decades. Scientists now have found significant decreases in

tumor size when advanced breast cancer patients are treated with any one of six drugs. Although these observations do not show any lenghtening of these patients' lives, they are essential first steps toward improved treatment for breast cancer in the future.

The National Cancer Institute screened more than 78,000 compounds for anti-cancer activity during 1972 and 1973, a significant increase from the approximately 15,500 compounds screened in 1971. Fifteen drugs received Food and Drug Administration approval in 1973 for experimental use against human cancers, after stringent tests by NCI with animals. Five drugs received similar approval during 1972.

Andrimycin, one particular experimental drug, has been found to have activity against a broader range of cancers than any other known drug. This includes breast cancer and lung cancer, the leading cancer killer among American men and now the third greatest cause of cancer deaths among women as well. Research now centers on developing less toxic forms of this promising drug.

Investigators at several institutions have shown that a person's immune system can be stimulated to defend against cancer and further research to develop this treatment approach is underway.

The treatment of cancer is more effective when the disease is detected in an earlier and more localized stage, and progress is also being made in the detection of cancer.

X-ray examination used in combination with physical examination in mass screening for breast cancer has resulted in a one-third reduction of the death rate from that disease over a five-year period among study populations.

A study of 18,000 persons over age 50 who had over the past 25 years received periodic examinations of the lower colon, and removal of polyps or other precancerous conditions showed that the rate of colon cancer among these individuals was only 15 percent of that expected if they had not been examined regularly.

Scientists are using immunologic techniques to detect cancer-related chemicals, or "markers," in the blood or urine of persons with cancer. One such marker, called carcinoembryonic antigen (CEA), may be useful in combination with other tests for early detection and follow-up of cancers of the digestive system, particularly colon cancer.

Advances in detection and treatment will cure or prolong the lives of cancer patients, but understanding the causes of cancer may lead to its prevention as well. Progress is also being made in this area.

The National Cancer Institute has significantly expanded its program to identify cancer-causing chemicals in the environment. Approximately 445 chemicals are now being tested in two-year and three-year studies with animals. The tests are under way at 20 laboratories, including the Frederick Cancer Research Center, converted by Presidential mandate from a biological warfare center, at Fort Detrick, Maryland.

Screening tests that may identify cancer-causing chemicals in as little as two weeks (normally a very time consuming process) are being developed by NCI scientists.

Research efforts have found asbestos increasingly as a pollutant in both air and water, and suggested that its apparent role as one cause of lung cancer may depend on the shape of asbestos particles rather than on their chemical nature.

Studies of cancer among various population groups has pointed to other causes of the disease. A hormone, diethylstilbestrol, used for a number of years to prevent miscarriage among pregnant women, has been linked with the occurrence of vaginal cancer in their daughters 15 to 22 years later. Other studies are finding relationships between dietary patterns and cancers of the digestive tract in Japanese migrants to Hawaii, California, and British Columbia.

No virus has yet been found to cause human cancer, but scientists are accumulating evidence of the association of several viruses with breast cancer, leukemia, cancer of the cervix, and other forms of cancer. A battery of highly sensitive biochemical and immunologic tests have been developed for this research. These tests have been used to show that at least two candidate human cancer viruses are instead of animal origin, important information which allows NCI to direct its resources elsewhere.

Totally new approaches for cancer control and prevention may ultimately emerge from fundamental research into the life processes of cells, and are presently being developed.

An artificial and potentially functioning gene has been synthesized for the first time. Years of further research may lie ahead, but scientists hope artificial genes can be used to learn how cancer starts—and how it can be stopped.

Genes direct the synthesis of enzymes that cells need to function. There is new evidence that several enzymes may appear only in cancer cells. If these enzymes are essential for the survival of cancer cells, blocking the enzymes may kill the cells while leaving normal cells unharmed.

Turning to its second thrust, the National Cancer Program has posted an excellent record in delivering research results to the people. The program is doing what can be done, now, for the cancer patient and those at risk of cancer.

Nine major medical institutions across the country have established Comprehensive Cancer Centers. Three pre-existing Centers of comparable scope have been strengthened. The remaining six Centers called for by the National Cancer Act will be in operation by July 1, and additional Comprehensive Centers are being planned. These Centers engage in the full range of basic and clinical cancer research. They train professional manpower required for the National Cancer Program. They assist other institutions in their surrounding areas in providing the best possible programs of cancer prevention, detection, diagnosis, treatment and rehabilitation.

The Cancer Control Program, also called for by the National Cancer Act, has been firmly established. This new Program is speeding the application of research advances through relatively short-term projects conducted in and out of major centers.

In cooperation with the American Cancer Society, 20 breast cancer detection projects have been established throughout the country. More than 100,000 women will be screened annually to find breast cancers in the earliest possible stage—when this leading cause of cancer death among American women is most curable.

A network of more than 100 community hospitals is being established to demonstrate effective new treatments for acute lymphocytic leukemia, Hodgkin's disease and non-Hodgkin's lymphomas.

Collaboration with the HEW National Clearing-house for Smoking and Health is aimed at reducing the number of cancers caused by smoking.

Several centers and hospitals are developing model cancer rehabilitation programs that can be replicated in community hospitals as well as the large centers for cancer care.

The National Cancer Institute also conducts and supports clinical research involving all 36 major forms of cancer. More than 20,000 patients, 1,600 physicians and 320 cancer centers and other hospitals throughout the country are participating in these programs. This is the frontline where gains are gradually being made in treating cancer. In addition, the participating physicians and hospitals are integral parts of the nation's medical care system, routinely caring for cancer patients not enrolled in studies. This integration of effort strengthens cancer care generally, and speeds research advances to all patients.

Although progress against cancer since the passage of the National Cancer Act of 1971 has been dramatic, the Committee feels that certain problem areas do exist which have tended to impede the National Cancer Institute's ability to conduct the program in the most efficient and effective manner. A major area of concern has been the failure of the Executive Branch to fund Congressional appropriation bills, through veto and impoundment. These practices have made the conduct of the National Cancer Program, as well as all of DHEW programs, tenuous and has caused delays in the implementation of many aspects of the National Cancer Program. The Committee further feels that:

(1) The NCI has been severely limited in its efforts to secure sufficient numbers of personnel to conduct its activities by reduced DHEW personnel ceilings and an inadequate number of supergrade positions. The original Congressional intent of Section 410(1) of P.L. 92–218 was to provide the National Cancer Program with 50 experts or consultants over and above the normal DHEW position ceilings for the National Cancer Institute. The intent of the law, in this case, has not been complied with.

(2) The Director, NCI, has been prevented from conducting a full range of communications, information and public affairs activities in support of the National Cancer Program because of the centralization of much of the responsibility to conduct these activities in the NIH and DHEW and accompanying 25% reduction in NCI public affairs personnel.

(3) There has been an insufficient number of NIH central staff to support the NCI as well as the other National Institutes. Examples of the types of central staff in short supply at NIH are nurses and other Clinical Center support staff, housekeepers, security personnel, and personnel for the renovation of facilities.

(4) The amount of time incurred between the submission of a

grant application or contract proposal and approval or disapproval is excessive. Improved regulations and streamlined procedures are urgently needed to facilitate the decision-making process in this area.

(5) The Director, NCI, has been limited in his authority under Section 410(c)(1) to award grants not exceeding $35,000 without review and recommendation of approval by the National Cancer Advisory Board, through a DHEW General Counsel decision that the $35,000 specified must include both direct and indirect costs. This decision significantly limits the number of approved grants the Director may choose to award and reduces the effectiveness of the original Congressional intent of this Section.

(6) The Director, NCI, has not been permitted to exercise the independent contracting authority given him in Section 410(7) of P.L. 92–218.

The Committee was distressed to learn that the NCI is unable to make grants for new construction, alteration, or renovation of basic research laboratory facilities. A further concern is any possible limitation of the number of new clinical cancer research and demonstration centers (Comprehensive Cancer Centers) that can be funded under section 408(a). The Act now calls for 15 new centers to be assisted and it was felt that this limitation severely restricts the National Cancer Program from carrying out its goal of demonstrating the latest methods of cancer diagnosis and treatment to health practitioners across the United States. Comprehensive Cancer Centers are not a medical delivery system nor are they expected to treat cases of cancer in their regions except when research is done as an adjunct to the Centers' research and demonstration programs. They are expected to be geographically evenly distributed to allow for a significant impact on the quality of cancer care throughout the nation through effective demonstration and outreach programs.

During recent years, the balance among NIH programs has been undergoing a dramatic shift. This shift is characterized by the support of certain categorical disease areas at what seems to be the expense of others, and the favored support of special initiative research programs (contracts) over individual investigator initiated research (grants). The Committee appreciates the difficulty of the NIH in maintaining a balance among its programs during this period of overall level of declining funding and has become increasingly concerned about the problems created by this trend. The following tables show appropriations for NIH by institute in first real and then constant (1965=100) dollars and make the problem of program balance visible.

## TABLE III.—NATIONAL INSTITUTES OF HEALTH COMPARABLE APPROPRIATIONS, FISCAL YEAR 1965–75

[In thousands of dollars]

| Institute or program | 1965 | 1966 | 1967 | 1968 | 1969 | 1970 | 1971 | 1972 | 1973 | 1974 | President's budget, 1975 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| National Cancer Institute | 143, 429 | 157, 279 | 168, 458 | 172, 373 | 174, 509 | 181, 460 | 223, 633 | 372, 838 | 485, 317 | 551, 192 | 600, 000 |
| National Heart and Lung Institute | 115, 784 | 132, 331 | 154, 667 | 154, 141 | 153, 826 | 159, 195 | 182, 360 | 224, 389 | 290, 728 | 302, 915 | 309, 299 |
| National Institute of Dental Research | 19, 033 | 22, 492 | 26, 985 | 28, 229 | 28, 009 | 29, 120 | 33, 504 | 42, 366 | 45, 797 | 45, 565 | 43, 959 |
| National Institute of Arthritis, Metabolism and Digestive Diseases | 105, 224 | 115, 289 | 126, 912 | 130, 589 | 130, 985 | 134, 202 | 125, 095 | 145, 032 | 158, 082 | 159, 447 | 152, 961 |
| National Institute of Neurological Diseases and Stroke | 82, 085 | 95, 263 | [1] 109, 397 | 94, 231 | 95, 466 | 96, 818 | 93, 647 | 111, 557 | 124, 434 | 125, 000 | 119, 958 |
| National Institute of Allergy and Infectious Diseases | 68, 667 | 77, 094 | 88, 934 | 95, 259 | 97, 729 | 94, 200 | 92, 329 | 103, 986 | 107, 640 | 114, 000 | 110, 404 |
| National Institute of General Medical Sciences | 108, 658 | 121, 562 | 138, 306 | 145, 984 | 149, 343 | 150, 875 | 146, 557 | 166, 358 | 175, 281 | 176, 778 | 168, 329 |
| National Institute of Child Health and Human Development | 39, 364 | 51, 125 | 60, 565 | 62, 967 | 67, 798 | 72, 400 | 89, 222 | 112, 515 | 125, 949 | 130, 254 | 124, 897 |
| National Eye Institute | ---------- | ---------- | ---------- | 22, 040 | 22, 040 | 24, 142 | 28, 619 | 35, 555 | 36, 792 | 41, 631 | 39, 947 |
| National Institute of Environmental Health Sciences | 9, 181 | 15, 752 | 24, 054 | 16, 609 | 17, 154 | 17, 697 | 19, 361 | 25, 889 | 30, 364 | 28, 879 | 28, 684 |
| Division of Research Resources | 87, 635 | 96, 665 | 107, 880 | 122, 957 | 125, 753 | 131, 955 | 127, 149 | 130, 211 | 135, 791 | 133, 472 | 82, 700 |
| Fogarty International Center | 2, 462 | 2, 520 | 4, 464 | 3, 340 | 3, 390 | 3, 020 | 3, 732 | 4, 357 | 4, 666 | 4, 767 | 4, 784 |
| National Library of Medicine | 3, 858 | 9, 569 | 20, 090 | 19, 641 | 17, 889 | 19, 563 | 21, 430 | 24, 111 | 28, 488 | 25, 871 | 27, 738 |
| Office of the Director | 4, 984 | 5, 780 | 6, 107 | 9, 783 | 9, 783 | 10, 113 | 11, 074 | 11, 117 | 12, 618 | 12, 000 | 18, 124 |
| Buildings and Facilities | ---------- | ---------- | ---------- | ---------- | ---------- | 1, 900 | ---------- | 3, 565 | 8, 500 | 8, 000 | 3, 000 |
| Total | 790, 364 | 902, 721 | 1, 036, 799 | 1, 078, 143 | 1, 093, 674 | 1, 126, 660 | 1, 197, 712 | 1, 513, 846 | 1, 770, 447 | 1, 859, 771 | 1, 834, 784 |

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[1] Includes portion that established National Eye Institute.

## TABLE IV.—NATIONAL INSTITUTES OF HEALTH COMPARABLE APPROPRIATIONS IN CONSTANT DOLLARS (1965=100),[1] FISCAL YEAR 1965–75

[In thousands of dollars]

| Institute or program | 1965 | 1966 | 1967 | 1978 | 1969 | 1970 | 1971 | 1972 | 1973 | 1974 | President's budget, 1975 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| National Cancer Institute | 143, 429 | 153, 010 | 158, 803 | 156, 220 | 150, 894 | 148, 738 | 175, 069 | 282, 882 | 349, 652 | 372, 578 | 388, 727 |
| National Heart and Lung Institute | 115, 784 | 128, 739 | 145, 802 | 139, 696 | 133, 010 | 130, 488 | 142, 759 | 170, 250 | 209, 458 | 204, 755 | 200, 388 |
| National Institute of Dental Research | 19, 033 | 21, 882 | 25, 438 | 25, 584 | 24, 219 | 23, 869 | 26, 228 | 32, 144 | 32, 995 | 30, 800 | 28, 480 |
| National Institute of Arthritis, Metabolism and Digestive Diseases | 105, 224 | 112, 160 | 119, 638 | 118, 351 | 113, 260 | 110, 002 | 97, 929 | 110, 039 | 113, 892 | 107, 778 | 99, 100 |
| National Institute of Neurological Diseases and Stroke | 82, 085 | 92, 677 | [2] 103, 127 | 85, 401 | 82, 547 | 79, 359 | 73, 311 | 84, 641 | 89, 650 | 84, 494 | 77, 718 |
| National Institute of Allergy and Infectious Diseases | 68, 667 | 75, 001 | 83, 837 | 86, 332 | 84, 504 | 77, 213 | 72, 279 | 78, 897 | 77, 550 | 77, 058 | 71, 528 |
| National Institute of General Medical Sciences | 108, 658 | 118, 262 | 130, 379 | 132, 304 | 129, 134 | 123, 668 | 114, 731 | 126, 220 | 126, 283 | 119, 493 | 109, 057 |
| National Institute of Child Health and Human Development | 39, 364 | 49, 737 | 57, 074 | 57, 066 | 58, 623 | 59, 344 | 69, 847 | 85, 368 | 90, 741 | 88, 045 | 80, 918 |
| National Eye Institute |  |  |  | 19, 975 | 19, 058 | 19, 789 | 22, 404 | 26, 976 | 26, 507 | 28, 140 | 25, 881 |
| National Institute of Environmental Health Sciences | 9, 181 | 15, 324 | 22, 675 | 15, 053 | 14, 833 | 14, 506 | 15, 157 | 19, 643 | 21, 876 | 19, 521 | 18, 584 |
| Division of Research Resources | 87, 635 | 94, 041 | 101, 697 | 111, 435 | 108, 736 | 108, 160 | 99, 537 | 98, 794 | 97, 832 | 90, 220 | 53, 580 |
| Fogarty International Center | 2, 462 | 2, 452 | 4, 208 | 3, 027 | 2, 931 | 2, 475 | 2, 922 | 3, 306 | 3, 362 | 3, 222 | 3, 099 |
| National Library of Medicines | 3, 858 | 9, 309 | 18, 939 | 17, 800 | 15, 468 | 16, 035 | 16, 776 | 18, 294 | 20, 524 | 17, 487 | 17, 971 |
| Office of the Director | 4, 984 | 5, 623 | 5, 757 | 8, 866 | 8, 459 | 8, 289 | 8, 669 | 8, 435 | 9, 091 | 8, 111 | 11, 742 |
| Buildings and Facilities |  |  |  |  |  | 1, 557 |  | 2, 705 | 6, 124 | 5, 408 | 1, 944 |
| Total | 790, 364 | 878, 219 | 977, 375 | 977, 110 | 945, 676 | 923, 492 | 937, 617 | 1, 148, 593 | 1, 275, 538 | 1, 257, 112 | 1, 188, 717 |

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[1] Using implicit GNP price deflators.

[2] Includes portion that established NEI.

Several comments on these tables are appropriate. First, it is important to notice the major effects that inflation has had on the availability of real resources to the NIH. Between 1965 and 1975 the total NIH budget has increased from $790 million to $1,834 million. However, in constant dollars this has represented an increase to only $1,188 million, certainly not as much growth as the real dollar figures would suggest. Second, it is interesting to note that in constant dollars both the cancer, and heart and lung programs had diminishing real resources between 1967 and 1970. This suggests a large part of the underlying reason why the Congress enacted special legislation to support these two institutes. The effect of this legislation is obvious in that both institutes have had major increases in their real resources since the enactment of their legislation. The effect in the case of cancer has been more marked than that in the case of heart and lung diseases, which after a real boost in 1972 and 1973 apparently is again beginning to lose ground. For the rest of NIH available constant dollars have in fact been decreasing since the latter part of 1971 with a uniform loss by all institutes of real resources to inflation.

If the selection of a number of research programs for increased funding (cancer and heart being the largest cases) continues the result will be to severely limit the NIH's capabilities to effect a program balance so vital to the success of biomedical research. Biomedical research has reached the stage today that there are no longer sharp dividing lines between the various diseases and research disciplines. It was stated by numerous witnesses that there will be important contributions to cancer from basic biomedical research aimed at other diseases, and that there will also be important contributions for other disease areas from cancer research. But it is also true that a great deal of the increased funding for these institutes is expected to be devoted to such highly focused activities that such cross-fertilization will be minimal. Therefore, the Committee takes the position that this country cannot afford to reduce the research efforts of other NIH Institutes and urges a higher priority to budget increases for all of NIH. Also, because it is estimated that in constant dollars the total allocations for investigator-initiated programs (grants) has declined by 10% since FY72 while expenditures for contract support at NIH for the same time period increased 16%, it is recommended that this trend be reversed and support stabilized for projects initiated by individual investigators.

The Committee is deeply concerned about the lack of support by the Executive Branch for the training grant and fellowship program. It is absolutely essential that the training of scientists, researchers and physicians go forward in all areas of biomedical research, cancer as well as other areas. When the high cost of medical care in this country is examined, it becomes clear that we cannot afford to economize on the effort to produce the people who will make the discoveries that will facilitate prevention or simplify cure.

## PROPOSED LEGISLATION

The Committee feels it is appropriate to extend the authorizations of the National Cancer Act to assure the continuance of the national program against cancer. The Members are particularly concerned that the activities of the National Cancer Program proceed uninterrupted and with a maximum flexibility of effort. Therefore, the Committee has recommended minimum changes in the law and a general three-year extension. While it is pleasing that there has been significant progress against cancer since the passage of the National Cancer Act of 1971, nevertheless, as with most major program expansions, there have been some problems and growing pains.

These are related primarily to the availability of certain types of personnel, the processing time for grants and contracts, the scope of the NCI's public information program and the contract authorities exercised by the Director of the NCI. In addition, the committee has also been concerned that past budgetary policies of the Administration have affected the budget for the cancer program. However, in contrast to the great strides which have been made, these problems are manageable. Further, the committee is heartened by the Administration's new policy in dealing with enacted appropriations. A number of modifications have been recommended to facilitate an improved cancer research effort. These include increasing the number of authorized supergrades for cancer experts from 50 to 100, removing indirect costs as a component of the $35,000 ceiling on non-Council approved grant awards, and removing the current limitation of 15 on the number of Comprehensive Cancer Centers authorized under the act. Moreover, the committee urges that the Director of the National Cancer program be allowed to exercise his full statutory authority relative to the contract process and public information activities.

With the proposed legislative and programmatic improvements, the NCI programs will be on an even more stable footing. Problem areas will be kept under close surveillance and will be brought to the attention of the House if continued difficulties with the expanded cancer research programs are encountered. The changes and accompanying committee recommendations which have been made are described below and in the section-by-section analysis in more detail.

### *Nutrition programs*

The Committee heard testimony from the Candlelighters Association, which was confirmed by the Director of NCI, that the NCI's programs of support for nutrition were inadequate. Several specific projects to study the relationship between the nutritional status of cancer patients and their survival, and the relationship of diet to the cause of cancer were described. However, indications were given that the NCI has not mounted a general program of collection and disseminaation to people concerned with cancer and afflicted by it of information about the relationship between nutrition and cancer. For this reason the proposed legislation contains an amendment designed to encourage the Cancer Institute to improve its performance in these areas. The amendment will require the Institute to gather information on the relationship between nutrition and cancer and the roll of nutrition in the treatment of cancer patients and then to make this information generally available to all those who would be interested in or aided by it.

### *Increases in authority for the NCI*

The Committee heard testimony, described above under "Need for Legislation," that there have been a variety of areas in which the legislation presently gives inadequate authority to the director of the NCI for the effective operation of the National Cancer Program. In some cases the need is for more legislative authority while in other cases the need is for a more explicit direction that the NCI be allowed to function free of interference from the rest of HEW and the OMB.

Some evidence was presented to the Committee that the personnel available to the NCI has been inadequate in number and grade. Particularly the Committee was told that positions available to the NCI are on some occasions not being released by HEW for actual use by the Cancer Institute. For these reasons the legislation adds to the authority for the director of NCI to prepare and submit budget estimates, authority for him to include with the budget estimates of his personnel needs for the operation of the national cancer program. These budget and personnel estimates are to be submitted directly to the President for review and transmittal to the Congress. It is the Committee's hope and intention that positions made available to the NCI by the Appropriations Committees and by the OMB in response to its estimates of its needs will be made directly available to NCI by OMB. The inclusion of the requirement for specific personnel estimates in the budget is intended to make possible a public comparison of estimated needs and available resources. This public comparison should also make it possible to identify where the responsibility lies for any inadequacy in the number or quality of the personnel available to the NCI.

Second, the Committee was concerned that the interpretation by HEW of the provisions in the legislation which allow the Director of NCI to make direct grants without national advisory board review has been such as to limit this granting authority to less than the $35,000 direct cost limit intended in the original legislation. For this reason the legislation contains amendments specifying that the $35,000 amount applies to the direct rather than the direct and indirect costs associated with the grant. This is intended by the Committee to increase the effective amount of any grant which the Director of the NCI can make without national advisory board review.

Third, the legislation originally provided to the NCI authorizes the conduct of training for individuals concerned with cancer and the use of training stipends, fellowships, and career awards for this purpose. The original legislation includes a provision that this training is to be undertaken "where appropriate". This provision has been interpreted by HEW as allowing them to find that such training is never appropriate and therefore as allowing them to deny the NCI the opportunity to conduct such training. Since it was clearly the original legislative intent that such training be undertaken, the proposed legislation deletes the phrase "where appropriate" so that the director of NCI's authority for training is unambiguous and cannot be curtailed by HEW or OMB.

Fourth, the original legislation contains authority for the Director of NCI to hire up to 50 experts and consultants over and above any personnel ceilings and limitations placed upon him by HEW. Again, testimony was heard that the Director's authority in this regard has been circumscribed and that he therefore has been unable to obtain as many experts and consultants as the program could use. For this reason the legislation increases the limit on how many experts and consultants may be hired to 100. The Committee wishes to reiterate its intent that the director of NCI be unfettered in his use of this authority and that these positions not be considered in any personnel ceilings or allocations available to the NCI.

Finally, substantial testimony was presented to the effect that existing research facilities, especially those for research in biohazard control, are inadequate in number and in many cases outdated, run down, and in need of renovation. For this reason the legislation contains direct authority for the director of the NCI to make grants for the construction, renovation, or alteration of basic research facilities.

### *Comprehensive cancer centers*

Impressive testimony was heard concerning the need and desirability for the National Cancer Program to have the flexibility to designate sufficient Comprehensive Cancer Centers to put into the mainstream of modern medicine information about new discoveries, new and improved methods of diagnosis, and new approaches to treatment that emanate from the research activities of the National Cancer Program. The outreach of the 15 new and 3 pre-existing Comprehensive Centers is insufficient to serve the entire United States. Such major cities as St. Louis, San Francisco, Philadelphia, Atlanta, New Orleans, Chicago, and many others are without Comprehensive Centers and the Committee therefore recommends striking the present limitation to 15 on new centers from the Act to permit the NCI to designate and support the growth of enough centers to place the vast majority of citizens in the United States within a reasonable distance of a Comprehensive Cancer Center.

### *Information programs*

The NCI is presently involved in many crucial information programs. It answers more than 18,000 public inquiries a year. Many of these come from people with cancer seeking advice on where to find the best possible care or on their own appropriate handling of their disease. Others seek advice on how to prevent cancer. Many more would turn to the NCI if they knew that information of a kind that is often not available in their local communities could be obtained from the program. Many information programs are also operated to support researchers and practicing physicians. These include an International Cancer Research Data Bank and a Journal of the National Cancer Institute. On the other hand, the Committee heard some testimony that impressive and appropriate as these programs are, the NCI has inadequate resources and is doing an inadequate job of sharing with the research, professional, and public communities the results and discoveries of the cancer program which could be used to improve the prevention, treatment and rehabilitation of cancer.

For these reasons the legislation includes specific authority for the Director of the NCI to engage in the dissemination and interpretation of new and existing knowledge and information produced by the cancer program to the concerned communities including researchers, practicing physicians, and the general public. This new authority is not intended as a new Federal public relations program but rather as a mandate for the appropriate dissemination of new and existing knowledge to those who need to benefit from it. As such this authority and its exercise by the NCI should not be restricted or curtailed by HEW. The Committee is impressed that part of the reason why the NCI has been criticized for the inadequacy of its information programs is that these programs have been slowed and limited by the elaborateness of the reviews and approvals which must be sought for them in the bureaucracy surrounding the NCI. Since the Committee feels that these activities on the part of the NCI are crucial to the program and appropriate for it, it is intended that this limitation and interference by HEW will be stopped.

*Peer Review of Grant Applications and Contract Projects*

The Committee is aware that, under the Public Health Service Act the NIH institute advisory councils, composed of nonfederal scientific experts and laymen, make recommendations on funding awards for NIH or NIMH administered research grant applications. At the present time, although not required by law (except for the National Cancer Institute), grant applications are initially reviewed by peer groups of scientific experts (free of any conflict of interest) who evaluate the applications on the basis of scientific merit and make recommendations to the advisory council. Research and development contract projects administered by the NIH or NIMH are not required by law to undergo peer review. The Committee understands that the NIH has long used peer groups in a highly decentralized system for review of research contract proposals and has begun to establish a central referral and surveillance system on these reviews to capture data. These moves are expected to insure equity and high quality research throughout all operating elements of the agency.

The Committee has been told that the most significant component in the research contract process is deciding what should be investigated/developed, e.g., defining the "project." The term "project" is used by the NIH to define a circumscribed activity which (a) involves investigation designed to acquire new knowledge and/or mobilization of resources to support the acquisition of new knowledge and (b) involves one of the following: (1) a single contract, (2) a small number of contracts which are similar in scope and content, or (3) a small number of contracts which are interdependent. If project selection is well done, the succeeding steps are well within the scope of in-house competence: writing the RFP (Request for Proposals) and determining which performers submitting proposals are equipped (have the resources and technical competence) to perform the well defined and circumscribed tasks. Under prevailing practice, these tasks are defined in the project statement developed by the staff under the direction of the peer group. If the project cannot be well defined and the RFP seeks performers who will provide innovative approaches in a particular problem area, then a peer group is used to supplement in-house staff in the selection of the most meritorious proposals.

The Committee supports the existing peer review system and concludes that the peer review system of the NIH must be maintained and strengthened, and extended to cover review of the research and development contract projects. The Committee has therefore established a requirement in the legislation for peer review by assembled groups of qualified independent scientific experts of all grant applications and research and development contract projects administered by the NIH and the NIMH.

The provisions of the National Cancer and Heart Acts, allowing the Institute Directors to approve grants under $35,000 with peer review but without advisory council approval, would be retained in law [sections 402(b) and 419(A)(c) of the Public Health Service Act].

It is the intent that this new mandated peer review system use, to the maximum extent possible, existing mechanisms.

This is not a mandate to set up an entirely new peer review system, but rather to build upon the existing system. The Committee also intends that the prevailing methods of the existing system to avoid conflicts of interest among peers on the assembled groups be maintained.

The importance of the peer review process mandated in the new section 455 cannot be overemphasized. The very existence of biomedical and behavioral research of the magnitude now supported by the Federal government makes it essential that a system of research administration be specified. So far the most productive the United States has known, the present peer review system relies on spreading decisional responsibility throughout the recognized top ranks of United States biomedical and behavioral scientists.

The Committee does wish to note that despite the generally excellent results which the existing peer review system has produced, there has been some criticism that on occasion it operates in a manner which is unfair to individual researchers. It is hoped that the NIH in implementing the provisions of the new section will consider the extent and seriousness of such criticism and will take whatever steps are necessary to insure that a just and proper recourse is available to every unsuccessful applicant who wishes to appeal an adverse decision. In this connection the Committee feels that, if the present appeals mechanisms are determined to be insufficient, it would be appropriate to consider the creation of an independent appeals process through which scientists who feel that the peer review system has treated them inappropriately can seek redress of their grievances.

## SECTION-BY-SECTION ANALYSIS OF H.R. 13053

*Section 1.*—Provides that the Act may be cited as the "National Cancer Amendments of 1974".

*Section 2.*—Amends section 402(b) of the Public Health Service (PHS) Act in two places. First, by striking "in amounts not to exceed $35,000" in paragraph 1 and inserting in its place "if the direct costs of such research and training do not exceed $35,000, but only". Second, by striking "in amounts exceeding $35,000" in paragraph 2 and inserting in its place "if the direct costs of such research and training exceed $35,000, but only".

Section 402(b) of the PHS Act contains the granting authority for cancer research or training grants for the director of the National Cancer Institute (NCI). It presently provides that he may make grants in amounts not exceeding $35,000 without the review and recommendation of the National Cancer Advisory Board prescribed by section 403(c) of the PHS Act, but must have such review and recommendation in making grants in amounts exceeding $35,000. In administering the provisions of this section, the Department of HEW has interpreted the $35,000 amount to include both direct and indirect costs associated with the making of a grant. This amendment clarifies the Committee intent that the $35,000 amount be interpreted to include only the direct costs of a grant. The amendment thereby increases the effective amount of a grant which can be made by the director of the NCI without review and recommendation by the National Cancer Advisory Board.

*Section 3.*—Amends section 407(b)(4) of the PHS Act by striking out "all data" and inserting in its place "information (including information respecting nutrition programs for cancer patients and the relationship between nutrition and cancer)".

Section 407(b)(4) of the PHS Act presently provides the director of the NCI with authority to collect, analyze, and disseminate all data useful to the cancer program. The amendment changes the phrase "all data" to "information", a term which the Committee considers both more general and more feasible than the term "all data". In addition the amendment adds to the Act specific reference to the collection of information concerning nutrition programs for cancer patients and the relationship between nutrition and cancer. It is intended that this amendment allow the program to explore both the role of appropriate nutrition in the treatment and rehabilitation of people with cancer and the role of nutrition in causing cancer.

*Section 4.*—Amends section 407(b)(7) of the PHS Act by striking out the phrase "where appropriate". Section 407(b)(7) presently provides the director of the national cancer program with authority to support the training of manpower for the national cancer program through the use of training stipends, fellowships, and career awards. As presently written this section indicates that training stipends, fellowships, and career awards are to be available to the director of the national cancer program "where appropriate." The Administration has recently announced that the use of these training devices is "never appropriate" and thereby denied them to the national cancer program. This was not the Committee's intent in including the phrase "where appropriate" and the present amendment underlines that intent by removing the qualifying phrase in order to assure that training stipends, fellowships, and career awards are always available to the national cancer program for the training of needed manpower.

*Section 5.*—Amends section 407(b)(9)(A) of the PHS Act by inserting after the phrase "budget estimate" the new phrase "(including an estimate of the number and type of personnel needed for the national cancer program)".

Section 407(b)(9)(A) provides authority to the director of the NCI to prepare and submit directly to the President for his review and transmittal to the Congress an annual budget estimate for the national cancer program. This amendment is designed to insure that the budget estimate includes an estimate not only of the dollar resources needed by the national cancer program, but also of needed personnel resources.

*Section 6.*—Amends section 408(a) of the PHS Act by striking out "15".

Section 408(a) of the PHS Act provides the director of the NCI with authority to establish centers for clinical research, training, and demonstration of advanced diagnostic and treatment methods relating to cancer. The section presently limits this authority to the establishment of 15 such centers and the suggested amendment removes this limit and allows the director to establish as many centers as he finds to be appropriate.

*Section 7.*—Amends section 409(b) of the PHS Act containing authorizations of appropriations for cancer control programs by authorizing appropriations in fiscal year 1975 of $50 million, 1976 of $65 million, and 1977 of $85 million.

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*Section 8.*—Amends section 410 of the PHS Act concerning the authority of the director of the NCI in several respects. First, increases from 50 to 100 the number of experts or consultants whose services the director is authorized to obtain, if authorized by the National Cancer Advisory Board. Second, adds a new subparagraph 9 authorizing the director of the NCI to award grants for new construction as well as alterations and renovations for improvement of basic research laboratory facilities, including those related to bio-hazard control, as he finds necessary for the national cancer program. Third, designates the existing section 410 as section 410(a) and adds a new section 410(b) authorizing the director of the NCI to provide and contract for a program to disseminate and interpret on a current basis, for practitioners and other health professionals, scientists, and the general public new scientific and other information respecting the cause, prevention, diagnosis and treatment of cancer. The new section 410(b) further provides that the director of the NCI shall include in the annual report required by section 410A(b) a report on the progress, activities, and accomplishments of, and expenditures for, the information services of the national cancer program.

In increasing the number of experts and consultants available to the NCI from 50 to 100, the legislation responds to testimony heard that such increased resources would facilitate the work of the NCI. It is not intended that these additional experts and consultants be considered or included in the number of positions counted by the NCI against its position ceiling allocated from the Office of Management and Budget.

Similarly, the new authority for construction grants for either new construction or alterations or renovations of basic research laboratory facilities is responsive to testimony heard that there were an inadequate number of such facilities and that many such facilities were outdated and in need of modernization. The term "bio-hazard control" refers to the control of aspects of our environment which are likely to be hazardous to human biology. In the context of cancer, as here, the phrase would refer to programs designed to control man's exposure to or damage by chemicals, viruses, or forms of radiation which are likely to cause cancer. Some of the work currently being performed at the Frederick Cancer Research Center (the former Ft. Detrick in Frederick, Maryland) would constitute an example of bio-hazard control activities.

The new authority for the director of the NCI to provide or contract for a program to disseminate and interpret existing and new scientific and other information respecting cancer is responsive to the Committee's desire that the results of the national cancer program be made available as early and understandably as possible to all concerned communities. It is responsive to the often heard charge that the work of the NIH and its various institutes is not as generally available to practitioners and the public as would be desirable. The program called for is not intended to be a new public relations effort on the part of the bureaucracy but rather a more effective effort than that to date to make existing and new knowledge available throughout the nation. The requirement that the NCI's annual report include a report on the information programs conducted by the national cancer program and their costs should be understood to include a report on activities conducted under this section as well as sections 410(a)(8), 407(b)(4), and other authorities.

*Section 9.*—Amends section 410c of the PHS Act which authorizes appropriations for the national cancer program by authorizing appropriations for fiscal year 1975 of $750 million, 1976 of $830 million, and 1977 of $985 million.

*Section 10.*—Amends part G, containing administrative provisions, of Title IV of the PHS Act by adding a new section 445 to that part. Provides that the new section 455 shall be entitled "Peer Review of Grant Applications and Contract Projects". The new section 455 requires the Secretary of HEW to require appropriate scientific peer review of:

> (1) applications made after the effective date of regulations implementing the new section for grants under the PHS Act for biomedical and behavioral research; and
>
> (2) biomedical and behavioral research and development contract projects administered after such effective date. The scientific peer review is to conform to regulations which are to be prescribed after consultation with the Director of the NIH, and, where appropriate, the Directors of the National Institute of Mental Health, the National Institute on Alcohol Abuse and Alcoholism, or the National Institute on Drug Abuse.

The regulations requiring scientific peer review are to the extent practicable to require that the review be conducted:

> (1) in a manner consistent with the system for scientific peer review applicable on the date of enactment of this Act to applications for grants under the PHS Act for biomedical and behavioral research and to biomedical and behavioral research contract projects administered by the institutes listed above, and
>
> (2) by peer review groups performing such review on or before such date. The members of any peer review group established under the regulations are to be individuals who by virtue by their training or experience are imminently qualified to perform the review functions of the peer review groups, and not more than one-fourth of the members of any peer review group established under the regulations are to be officers or employees of the United States.

*Section 11.*—Amends section 301(h) of the PHS Act providing authority to the Secretary of HEW for contracting for research by deleting the phrase "during the fiscal year ending June 30, 1966, and each of the eight succeeding fiscal years."

The deletion of the quoted phrase has the effect of making the research contracting authority in section 301(h) a permanent authority for the Secretary of HEW.

## AGENCY REPORTS

Agency reports have not been received on H.R. 13053 or any of its similar predecessors. However, the following letter from President Nixon to Secretary of Health, Education, and Welfare Weinberger indicates the administration's general support for the extension of the National Cancer Act contained in the legislation.

THE WHITE HOUSE,
*Washington, January 29, 1974.*

Hon. CASPAR WEINBERGER,
*Secretary of Health, Education, and Welfare,*
*Washington, D.C.*

DEAR CAP: It has come to my attention that you will appear tomorrow at Senate hearings called to consider the extension of the National Cancer Act of 1971 when it expires on June 30. I want you to know that I strongly support an extension of this Act with whatever improvements might be made in consultation between the Executive Branch and the Congress.

I continue to have strong and continuing interest in this program. I remain just as committed to the attack on cancer as I was when I signed the original legislation on December 23, 1971. Our joint efforts with the Congress in this area have provided an excellent example of the ability of the Executive and Legislative Branches to work together in dealing with a major problem.

I have followed progress on the attack on cancer carefully. In addition, I have met with Benno Schmidt and other members of the President's Cancer Panel and have reviewed their report and the report of the National Cancer Advisory Board with great interest. It is my feeling that considerable progress has been made in the attack on cancer in recent years and that there is much hope for additional knowledge that can be developed in the future.

That is why I plan to ask for an additional $100 million above last year's request of $500 million for the expanded attack on cancer in the budget that I will be submitting to the Congress next Monday. I realize that this will result in spending over $415 million more for this effort next fiscal year than was available the year I took office, but I think the dual goals of an expanded research effort to find the causes of cancer along with more intensive demonstration and education programs to help prevent and control cancer warrant this support.

I hope you will share my strong interest in this program with the members of the Committee and express my appreciation for their past efforts in enacting the National Cancer Act of 1971.

Sincerely,

RICHARD NIXON.

## CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3 of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

# PUBLIC HEALTH SERVICE ACT

* * * * * * *

## TITLE III—GENERAL POWERS AND DUTIES OF PUBLIC HEALTH SERVICE

### Part A—Research and Investigation

### IN GENERAL

Sec. 301. The Surgeon General shall conduct in the Service, and encourage, cooperate with, and render assistance to other appropriate public authorities, scientific institutions, and scientists in the conduct of, and promote the coordination of, research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and impairments of man, including water purification, sewage treatment, and pollution of lakes and streams. In carrying out the foregoing the Surgeon General is authorized to—

(a) * * *

* * * * * * *

(h) Enter into contracts [during the fiscal year ending June 30, 1966, and each of the eight succeeding fiscal years], including contracts for research in accordance with and subject to the provisions of law applicable to contracts entered into by the military departments under title 10, United States Code, sections 2353 and 2354, except that determination, approval, and certification required thereby shall be by the Secretary of Health, Education, and Welfare; and

* * * * * * *

## TITLE IV—NATIONAL RESEARCH INSTITUTES

### Part A—National Cancer Institute

### TO BE A DIVISION IN NATIONAL INSTITUTES OF HEALTH

Sec. 401. The National Cancer Institute shall be a division in the National Institutes of Health.

### CANCER RESEARCH, AND SO FORTH

Sec. 402. (a) * * *

* * * * * * *

(b) Under procedures approved by the Director of the National Institutes of Health, the Director of the National Cancer Institute may approve grants under this Act for cancer research or training—

(1) [in amounts not to exceed $35,000] *if the direct costs of such research and training do not exceed $35,000, but only* after appropriate review for scientific merit but without the review and recommendation by the National Cancer Advisory Board prescribed by section 403(c), and

(2) [in amounts exceeding $35,000] *if the direct costs of such research and training do not exceed $35,000, but only* after appropriate review for scientific merit and recommendation for approval by such Board as prescribed by section 403(c).

* * * * * * *

NATIONAL CANCER PROGRAM

SEC. 407. (a) The Director of the National Cancer Institute shall coordinate all of the activities of the National Institutes of Health relating to cancer with the National Cancer Program.

(b) * * *

* * * * * * *

(4) Collect, analyze, and disseminate [all data] *information (including information respecting nutrition programs for cancer patients and the relationship between nutrition and cancer)* useful in the prevention, diagnosis, and treatment of cancer, including the establishment of an international cancer research data bank to collect, catalog, store, and disseminate insofar as feasible the results of cancer research undertaken in any country for the use of any person involved in cancer research in any country.

* * * * * * *

(7) Support appropriate manpower programs of training in fundamental sciences and clinical disciplines to provide an expanded and continuing manpower base from which to select investigators, physicians, and allied health professions-personnel, for participation in clinical and basic research and treatment programs relating to cancer, including [where appropriate] the use of training stipends, fellowships, and career awards.

* * * * *

(9)(A) Prepare and submit, directly to the President for review and transmittal to Congress, an annual budget estimate *(including an estimate of the number and type of personnel needed for the National Cancer Program)* for the National Cancer Program, after reasonable opportunity for comment (but without change) by the Secretary, the Director of the National Institutes of Health, and the National Cancer Advisory Board; and (B) receive from the President and the Office of Management and Budget directly all funds appropriated by Congress for obligation and expenditure by the National Cancer Institute.

* * * * * * *

### NATIONAL CANCER RESEARCH AND DEMONSTRATION CENTERS

SEC. 408. (a) The Director of the National Cancer Institute is authorized to provide for the establishment of [fifteen] new centers for clinical research, training, and demonstration of advanced diagnostic and treatment methods relating to cancer. Such centers may be supported under subsection (b) or under any other applicable provision of law.

* * * * * * *

### CANCER CONTROL PROGRAMS

SEC. 409. (a) The Director of the National Cancer Institute shall establish programs as necessary for cooperation with State and other health agencies in the diagnosis, prevention, and treatment of cancer.

(b) There are authorized to be appropriated to carry out this section $20,000,000 for the fiscal year ending June 30, 1972, $30,000,000 for the fiscal year ending June 30, 1973, [and] $40,000,000 for the fiscal year ending June 30, 1974, *$50,000,000 for the fiscal year ending June 30, 1975, $65,000,000 for the fiscal year ending June 30, 1976, and $85,000,000 for the fiscal year ending June 30, 1977.*

### AUTHORITY OF DIRECTOR

SEC. 410. (*a*) The Director of the National Cancer Institute (after consultation with the National Cancer Advisory Board), in carrying out his functions in administering the National Cancer Program and without regard to any other provision of this Act, is authorized—

(1) if authorized by the National Cancer Advisory Board, to obtain (in accordance with section 3109 of title 5, United States Code, but without regard to the limitation in such section on the number of days or the period of such service) the services of not more than [fifty] *one hundred* experts or consultants who have scientific or professional qualifications;

(2) to acquire, construct, improve, repair, operate, and maintain cancer centers, laboratories, research, and other necessary facilities and equipment, and related accommodations as may be necessary, and such other real or personal property (including patents) as the Director deems necessary; to acquire, without regard to the Act of March 3, 1877 (40 U.S.C. 34), by lease or otherwise through the Administrator of General Services, buildings or parts of buildings in the District of Columbia or communities located adjacent to the District of Columbia for the use of the National Cancer Institute for a period not to exceed ten years;

(3) to appoint one or more advisory committees composed of such private citizens and officials of Federal, State, and local governments as he deems desirable to advise him with respect to his functions;

(4) to utilize, with their consent, the services, equipment, personnel, information, and facilities of other Federal, State, or local public agencies, with or without reimbursement therefor;

(5) to accept voluntary and uncompensated services;

(6) to accept unconditional gifts, or donations of services, money, or property, real, personal, or mixed, tangible or intangible;

(7) to enter into such contracts, leases, cooperative agreements, or other transactions, without regard to sections 3648 and 3709 of the Revised Statutes of the United States (31 U.S.C. 529, 41 U.S.C. 5), as may be necessary in the conduct of his functions, with any public agency, or with any *person, firm, association, corporation, or educational institution;* [and]

(8) to take necessary action to insure that all channels for the dissemination and exchange of scientific knowledge and information are maintained between the National Cancer Institute and the other scientific, medical, and biomedical disciplines and organizations nationally and internationally[.]; *and*

*(9) to award grants for new construction as well as alterations and renovations for improvement of basic research laboratory facilities, including those related to biohazard control, as deemed necessary for the National Cancer Program.*

*(b)(1) The Director of the National Cancer Institute may provide and contract for a program to disseminate and interpret, on a current basis, for practitioners and other health professionals, scientists, and the general public new scientific and other information respecting the cause, prevention, diagnosis, and treatment of cancer.*

*(2) The Director of the National Cancer Institute shall include in the annual report required by section 410A(b) a report on the progress, activities, and accomplishments of, and expenditures for, the information services of the National Cancer Program.*

* * * * * * *

### AUTHORIZATION OF APPROPRIATIONS

SEC. 410C. For the purpose of carrying out this part (other than section 409), there are authorized to be appropriated $400,000,000 for the fiscal year ending June 30, 1972; $500,000,000 for the fiscal year ending June 30, 1973; [and] $600,000,000 for the fiscal year ending June 30, 1974; *$750,000,000 for the fiscal year ending June 30, 1975; $830,000,000 for the fiscal year ending June 30, 1976; and $985,000,000 for the fiscal year ending June 30, 1977.*

* * * * * * *

## PART G—ADMINISTRATIVE PROVISIONS

* * * * * * *

### *PEER REVIEW OF GRANT APPLICATIONS AND CONTRACT PROJECTS*

*SEC. 455. (a) The Secretary, after consultation with the Director of the National Institutes of Health, and, where appropriate, the Director of the National Institute of Mental Health, the National Institute on Alcohol Abuse and Alcoholism, or the National Institute on Drug Abuse, shall by regulation require appropriate scientific peer review of—*

(1) *applications made after the effective date of such regulations for grants under this Act for biomedical and behaviorial research; and*

(2) *biomedical and behavioral research and development contract projects to be administered after such effective date through an institute established under this title, the National Institute of Mental Health, the National Institute on Alcohol Abuse and Alcoholism, or the National Institute on Drug Abuse.*

(b) *Regulations promulgated under subsection* (a) *shall to the extent practical, require that the review required by the regulations be conducted—*

(1) *in a manner consistent with the system for scientific peer review applicable on the date of the enactment of this section to applications for grants under this Act for biomedical and behavioral research and to biomedical and behavioral research contract projects administered by the institutes referred to in paragraph* (2) *of subsection* (a), *and*

(2) *by peer review groups performing such review on or before such date.*

*The members of any peer review group established under such regulations shall be individuals who by virtue of their training or experience are eminently qualified to perform the review functions of the groups and not more than one-fourth of the members of any peer review group established under such regulations shall be officers or employees of the United States.*

* * * * * * *

## SEPARATE VIEWS OF THE HONORABLE JOHN D. DINGELL

### PROGRAM BALANCE

During recent years the balance among NIH research programs has been undergoing a dramatic shift, characterized by the support of certain categorical disease areas at the expense of others, and the favored support of special initiative, or targeted research programs over individual investigator initiated research. This shift has resulted from a mixture of the always present pressure of the political process, the requirements of the orderly advancement of biomedical knowledge and the end of growth in the Administration's support for medical research. The NIH has been able to maintain a reasonable balance among its programs during periods of increasing overall support. Continuing this balance during periods of level or declining funding has been extremely difficult, for the advantage has been with the short-term, highly visible, publicly appealing programs. The essentially level budget for FY '75 proposed by the Administration for NIH with the large proposed increases in heart and cancer funding will contribute further to the shift in program balance that has been steadily occurring, unless the Congress addresses the issue of balance among research programs early in 1974, and establishes a position which accommodates an appropriate emphasis on targeted research and special initiatives but restores investigator initiated research efforts to a level more representative of the central role that they play in NIH's support of the entire spectrum of biomedical research activities.

These views will briefly examine the major issues involved in the question of program balance and suggest a more reasonable approach than that of the Administration. These views are being filed with the Committee's legislation supporting an attack on cancer because I strongly believe that, until the issues I will discuss are resolved, this kind of special disease legislation should be resisted. Such legislation, while supportive of a particular disease, of necessity robs other disease research efforts in a manner without rationale. Were cancer the only example I could hold my peace but recent years have also seen blindness, sickle cell anemia, diabetes, heart and lung diseases, digestive diseases, multiple sclerosis, Cooley's anemia, sudden infant death and aging played as variations on the same theme. Why not cystic fibrosis, Tay-Sach's disease, arthritis, hemophilia, birth defects, hypertension, or cirrhosis of the liver? The Committee would do better leaving the choice of research directions to scientists operating under carefully drawn legislative mandates and devoting its energies to assuring adequate support for those scientists.

## CATEGORICAL DISEASE AREAS

In the past several years, opportunities for research progress have been accorded priority in certain categorical disease areas at the expense of others. The effect has been to accelerate the probability of achievement in the management of some diseases while at the same time slowing down the development of opportunities for progress in many other disease areas. Primary among the areas selected for intensified support are cancer and diseases of the heart and lung. Major initiatives in these areas are clearly warranted. In addition to these disease areas, however, there are many others in which human suffering and losses to the Nation's economy are severe and where the probability for significant research progress is also good. The issue is one of balance among programs which deal with the entire range of disease problems.

### TRENDS

The following are some brief statistical highlights of recent trends in the NIH support of categorical disease areas. Note that all these figures would be much more disturbing if they were adjusted to show the effect of our continued uncontrolled inflation.

NIH RESEARCH SUPPORT

[Obligations in millions]

| | 1967 | 1970 | 1972 | 1973 | 1974[1] |
|---|---|---|---|---|---|
| Total, NIH research | 1,021 | 1,038 | 1,475 | 1,483 | 1,532 |
| Subtotal | 320 | 326 | 597 | 673 | 765 |
| National Cancer Institute | 165 | 175 | 373 | 426 | 500 |
| National Heart and Lung Institute | 155 | 151 | 224 | 247 | 265 |
| All other institutes and research divisions | 701 | 712 | 878 | 810 | 767 |

[1] President's budget.

INDEX OF GROWTH IN NIH RESEARCH SUPPORT

| | 1967 | 1970 | 1972 | 1973 | 1974 |
|---|---|---|---|---|---|
| Total, NIH research | 1 | 1.02 | 1.44 | 1.45 | 1.50 |
| Subtotal | 1 | 1.02 | 1.87 | 2.10 | 2.29 |
| National Cancer Institute | 1 | 1.06 | 2.26 | 2.58 | 3.03 |
| National Heart and Lung Institute | 1 | (.97) | 1.45 | 1.59 | 1.71 |
| All other institutes and research divisions | 1 | 1.02 | 1.25 | 1.16 | 1.09 |

PERCENTAGE DISTRIBUTION OF NIH RESEARCH SUPPORT

| | 1967 | 1970 | 1972 | 1973 | 1974 |
|---|---|---|---|---|---|
| Total, NIH research | 100 | 100 | 100 | 100 | 100 |
| Subtotal | 31 | 32 | 40 | 46 | 50 |
| National Cancer Institute | 16 | 17 | 25 | 29 | 23 |
| National Heart and Lung Institute | 15 | 15 | 15 | 17 | 17 |
| All other institutes and research divisions | 69 | 68 | 60 | 54 | 50 |

The President's budget for 1974 called for an increase of $92 million over the 1973 level in the total for the Cancer and Heart Institutes. This was to be accompanied by a $43 million decrease in the remaining research activities of the NIH. Thus, almost ½ of the increase provided for Cancer and Heart Research was to be at the expense of other research activities. The NCI, which in 1967 accounted for 16 percent of the NIH research total, consumed about ⅓ of all NIH research activities in 1974. The share of the NHLI has remained approximately level over the 1967–1974 period, but that of the other research institutes and divisions has dropped from 69 percent in 1967 to only about 50 percent in 1974.

### IMPLICATIONS

For fiscal 1975, the Heart and Lung Institute estimated its program needs at $365 million, an increase of $100 million over the 1974 level. The Cancer Institute has proposed a preliminary budget to the National Cancer Board at two levels, the lower of which was $610 million, an increase of $110 million over the 1974 level. If, in 1975, the research total for the NIH were held to the 1974 dollar level, this would bring the remaining I/RDs down to $557 million, a decline of 27 percent below the 1974 level. Cancer and Heart-Lung would then account for 64 percent of the research total of NIH while the remaining I/RDs account for 36 percent.

The problem of "program balance" presented here is not merely a question of aesthetics. It was never anticipated that the expanded programs in Cancer and Heart-Lung would be at the cost of the remaining biomedical research activities of the NIH. But this is precisely what seems to be happening. There is an overriding need to maintain the viability of the nation's fundamental biomedical research capability in all areas. Despite the fact that cancer and heart disease are major killers and have taken the center of the health research stage, there is strong evidence that significant unexploited research opportunities exist in all categorical areas and are growing. If the existing trend toward increasing research support to Cancer and Heart-Lung continues, the general effect on the nation's fundamental biomedical research capability will be harmful and a good deal of the previous investment in research in other areas will simply be lost.

No algorithm exists which leads either planners, managers or biomedical research experts to automatic agreement on what constitutes optimal program balance across the spectrum of diseases which comprise the NIH mission. In the absence of such a tidy pathway, reason and good judgment alone would indicate a violation of program balance when ½ or more of the Agency's resources are devoted to two disease areas. While it is undoubtedly true that some research supported by Cancer and Heart-Lung dollars will be on a fundamental level and may well have implications for other disease areas, it is also true that a great deal of the increased funding for these institutes is expected to be devoted to such highly focused activities that general spin-off will be minimal. In addition, the number of individuals afflicted each year by all the disease problems which NIH regards as central to its mission does not justify such a limited concentration of effort in certain areas at the expense of others.

## Special Initiatives

A number of research programs selected by the Executive Branch or by Congress for increased funding have continued to receive preferential treatment even though the general funding conditions which obtained at the time of selection have changed substantially. These programs have not only been funded at accelerated rates but, during periods of financial stringency they have continued to prosper with relative impunity. In addition, items in budgets have frequently been earmarked for narrow, highly specified purposes. The effect has been an expansion of "uncontrollable" expenditures and a reduction of funds available for "discretionary" use. The implications of this pattern under a level effort budget for FY 1975, are clear—a continued reduction in discretionary funds for use in meeting research opportunities in numerous other program areas. The issue is essentially another facet of the question of program balance.

Those programs in such a favored position can be described collectively as special initiative programs or targeted research. Each may have somewhat differing characteristics but all enjoy a unique funding position primarily growing out of the political process. These programs address specific goals in problem areas usually of high public visibility. The emphasis is usually on applied problems and technical development, and they often involve large scale, costly efforts. If they are to be productive and not wasteful of money or manpower, they should only be undertaken when there is an adequate scientific base and the assurance of a high probability of success.

The programs involved in the major cancer and heart and lung initiatives are in this special initiative group. Other examples are the mandated programs dealing with dental caries, digestive diseases, child health, population/reproduction and aging.

TRENDS

[Dollar amounts in millions]

| | 1968 | | 1973 | | Percent change 1968–73 |
|---|---|---|---|---|---|
| | Amount | Percent | Amount | Percent | |
| Total NIH research | $1,044 | 100 | $1,483 | 100 | 42 |
| Special initiative programs, total | 408 | 39 | 817 | 55 | 100 |
| National Cancer Institute—National Heart and Lung Institute | 336 | 32 | 673 | 45 | 100 |
| Initiative programs | 72 | 7 | 144 | 10 | 100 |
| All other biomedical research programs | 636 | 61 | 666 | 45 | 5 |

Special initiative programs have doubled over the 1968–73 period, while all other biomedical research programs have increased by about 5 percent. In 1973 discretionary programs accounted for 55 percent of all NIH biomedical research support, compared to less than 40 percent in 1968.

### IMPLICATIONS

With the Administration's essentially level effort budget for FY 1975, continued preferential funding for these programs as in the past can only lead to a further loss by NIH of the discretionary funds so vital to pursuing the range of research opportunities that exist in many other important program areas.

I believe that special interest programs play an important role in this Agency's quest for the solutions to disease problems. However, during periods when NIH is directed to discharge its responsibilities under a level effort budget which provides for no real program growth, these programs should compete for the allocation of resources equally with other biomedical research programs focused on the broad range of other health problems within the NIH domain. The background leading to the identification and funding of special initiatives must be carefully weighed against all the conditions and factors which shape the biomedical research plan for a given period.

The acquisition of new knowledge and hence, progress in medicine depends on the contributions of the creative individual. The evidence is clear that major innovations of significant impact and broad applicability emerge largely from the work of individuals and small groups pursuing ideas arising out of their own experience and reflecting their personal creativity. There is no evidence to suggest that this will be less true in the future than it has been in the past, or that any other approach will increase the rate of important discoveries. Yet, investigator initiated research fares less well in nonscientific decision-making than other highly visible programs. Periods of fixed and/or declining resources exacerbate conditions to the extent that the base of excellent investigator initiated research is steadily eroded. A level effort budget emphasizes the need to examine the current status of investigator initiated research to consider the consequences of continued erosion and to establish a position more reflective of the central role that investigator initiated research plays in the NIH support of biomedical research.

## Investigator Initiated Research

Investigator initiated research projects are an integral part of the great majority of research programs administered by the NIH. Such projects contribute to the entire spectrum of biomedical research from fundamental to applied. From investigator initiated research comes the innovations which are the basis of later developmental work. Innovations cannot be deliberately planned but occur when a creative individual is allowed to follow his own instincts. The investigator plans his research design very carefully in the light of existing knowledge, aiming for a high return of useful, important information on his investment of time and effort. NIH reviews all projects for scientific merit and program relevance and monitors and evaluates progress made. This is done regardless of whether the project was initiated by the investigator or by NIH and regardless of whether it is a part of a highly targeted program or not. While the investigator decides exactly what lead he is going to pursue, and how, NIH fits his work into the overall scheme and makes sure the program as a whole moves forward.

### TRENDS AND IMPLICATIONS

Investigator initiated research projects have been steadily eroding over the past six years or so. In FY 1972, the most recent year for which complete data are available, funding for the Institutes and research divisions of the NIH was almost 50 percent greater than it had been for the same I/RD's in FY 1967. Funding for the investigator initiated programs of those I/RD's, however, was only 16 percent greater. Real growth, of course, was much smaller. In constant dollars it is estimated that the total I/RD programs increased by almost 16 percent. Funding for investigator initiated research, however, *declined* by 10 percent. The number of projects supported is down by one-fourth from 1967 levels and the number of principal investigators supported has dropped by one-fifth. If current trends remain unchecked during FY 1975, further erosion will occur.

During FY 1975, the NIH must check this trend and stabilize its support of investigator initiated research projects at levels consistent at least with those of 1972 with suitable adjustment made for the deflating effect of inflation. This recommendation reflects the high priority given to this activity because of the central role it plays in the majority of NIH programs, all of which have as their goal the management and resolution of disease problems]

## CONCLUSION

The Committee's report contains two tables, tables III and IV, which show the budgets for the National Institutes of Health from 1965–1975, the first table in real dollars and the second table in dollars adjusted to show the effects of inflation. The report goes on to politely bemoan the negative effect which increased support for cancer and heart disease has had upon the rest of the NIH's institutes. Careful scrutiny of these tables will show that the real devastation of the other Institutes brought on by our support for cancer and heart disease research is much too severe to be polite about. In constant dollars every Institute except the NCI itself would have a decrease in its available real resources under the President's 1975 budget. Most of us have realized that NIH is no longer expanding. The truth is that except for NCI all of NIH is contracting. One cannot maintain an operation of the high quality which we have come to expect of NIH and diminish its resources at the same time. This loss of real resources and the lack of support from the Administration for the NIH certainly are two of the principal explanations for the essentially complete turnover of top staff which the NIH has experienced in the last year and a half.

It should be clear by now that my remarks are not intended as an attack on cancer, or on this legislation particularly. They are separate, not dissenting, views. The point is that the trends which I have decribed at the NIH are more important policy issues than is the adequacy or inadequacy of NIH's research on any one disease. The series of special disease bills which we have been writing represents an approach to the problems of the NIH comparable to trying to solve the ship Titanic's problem by repairing its lifeboats when the ship itself could be saved. The NIH would receive better attention from the Congress were we to deal directly with the real problems which I have described rather than continuing to exacerbate them.

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93D CONGRESS } HOUSE OF REPRESENTATIVES { REPORT
*2d Session* } { No. 93-1164

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# NATIONAL CANCER ACT AMENDMENTS OF 1974

JUNE 27, 1974.—Ordered to be printed

Mr. STAGGERS, from the committee of conference, submitted the following

# CONFERENCE REPORT

[To accompany S. 2893]

The committee of conference on the disagreeing votes of the two Houses on the amendment of the House to the bill (S. 2893) to amend the Public Health Service Act to improve the national cancer program and to authorize appropriations for such program for the next 3 fiscal years, having met, after full and free conference, have agreed to recommend and do recommend to their respective Houses as follows:

That the Senate recede from its disagreement to the amendment of the House and agree to the same with an amendment as follows:

In lieu of the matter proposed to be inserted by the House amendment insert the following:

## *Title I—Extension of Cancer Program*

*SEC. 101. This title may be cited as the "National Cancer Act Amendments of 1974".*

*SEC. 102. Section 402(b) of the Public Health Service Act is amended—*

*(1) by striking out "in amounts not to exceed $35,000" in paragraph (1) and inserting in lieu thereof "if the direct costs of such research and training do not exceed $35,000, but only"; and*

*(2) by striking out "in amounts exceeding $35,000" in paragraph (2) and inserting in lieu thereof "if the direct costs of such research and training exceed $35,000, but only".*

*SEC. 103. Section 407(b)(4) of the Public Health Service Act is amended by striking out "all data" and inserting in lieu thereof "information (including information respecting nutrition programs for cancer patients and the relationship between nutrition and cancer)".*

*SEC. 104. Section 407(b)(7) of the Public Health Service Act is amended by striking out "where appropriate".*

**2**

*Sec. 105. Section 407(b)(9)(A) of the Public Health Service Act is amended by inserting "(including an estimate of the number and type of personnel needed for the National Cancer Program)" after "budget estimate".*

*Sec. 106. Section 408(a) of the Public Health Service Act is amended by striking out "fifteen".*

*Sec. 107. (a) Subsection (a) of section 409 of the Public Health Service Act is amended by inserting before the period at the end thereof a comma and the following: "including programs to provide appropriate trials of programs of routine exfoliative cytology tests conducted for the diagnosis of uterine cancer".*

*(b) Subsection (b) of such section is amended by striking out "and" before "$40,000,000" and by inserting before the period at the end thereof a comma and the following: "$53,500,000 for the fiscal year ending June 30, 1975, $68,500,000 for the fiscal year ending June 30, 1976, and $88,500,000 for the fiscal year ending June 30, 1977".*

*Sec. 108. Section 410 of the Public Health Service Act is amended—*

*(1) by striking out "fifty" in paragraph (1) and inserting in lieu thereof "one hundred";*

*(2) by striking out "and" at the end of paragraph (7);*

*(3) by striking out the period at the end of paragraph (8) and inserting in lieu thereof "; and";*

*(4) by adding after paragraph (8) the following new paragraph:*

*"(9) to award grants for new construction as well as alterations and renovations for improvement of basic research laboratory facilities, including those related to biohazard control, as deemed necessary for the National Cancer Program."; and*

*(5) by inserting "(a)" after "410." and by adding after paragraph (9) the following new subsection:*

*"(b)(1) The Director of the National Cancer Institute shall provide and contract for a program to disseminate and interpret, on a current basis, for practitioners and other health professionals, scientists, and the general public scientific and other information respecting the cause, prevention, diagnosis, and treatment of cancer.*

*"(2) The Director of the National Cancer Institute shall include in the annual report required by section 410A(b) a report on the progress, activities, and accomplishments of, and expenditures for, the information services of the National Cancer Program."*

*Sec. 109. Section 410C of the Public Health Service Act is amended by striking out "and" before "$600,000,000" and by inserting before the period at the end thereof a semicolon and the following: "$750,000,000 for the fiscal year ending June 30, 1975; $830,000,000 for the fiscal year ending June 30, 1976; and $985,000,000 for the fiscal year ending June 30, 1977".*

*Sec. 110. The part H of the Public Health Service Act relating to the appointment of the Directors of the National Institutes of Health and the National Cancer Institute is redesignated as part I, section 461 of such part is redesignated as section 471, and such part is amended by adding at the end the following new section:*

### "PEER REVIEW OF GRANT APPLICATIONS AND CONTRACT PROJECTS

*"Sec. 472. (a) The Secretary, after consultation with the Director of the National Institutes of Health, and, where appropriate, the Directors of the National Institute of Mental Health, the National Institute on Alcohol Abuse and Alcoholism, and the National Institute on Drug Abuse, shall by regulation require appropriate scientific peer review of—*

*"(1) applications made after the effective date of such regulations for grants under this Act for biomedical and behavioral research; and*

*"(2) biomedical and behavioral research and development contract projects to be administered after such effective date through an institute established under this title, the National Institute on Alcohol Abuse and Alcoholism, or the National Institute on Drug Abuse.*

*"(b) Regulations promulgated under subsection (a) shall, to the extent practical, require that the review of grant applications required by the regulations be conducted—*

*"(1) in a manner consistent with the system for scientific peer review applicable on the date of the enactment of this section to applications for grants under this Act for biomedical and behavioral research, and*

*"(2) by peer review groups performing such review on or before such date.*

*"(c) The members of any peer review group established under such regulations shall be individuals who by virtue of their training or experience are eminently qualified to perform the review functions of the group and not more than one-fourth of the members of any peer review group established under such regulations shall be officers or employees of the United States."*

*Sec. 111. Section 301(h) of the Public Health Service Act is amended by striking out "during the fiscal year ending June 30, 1966, and each of the eight succeeding fiscal years".*

*Sec. 112. (a) The first sentence of section 471 of the Public Health Service Act (as so redesignated by section 110) is amended to read as follows: "The Director of the National Institutes of Health shall be appointed by the President by and with the advice and consent of the Senate; and the Director of the National Cancer Institute shall be appointed by the President."*

*(b) The amendment made by subsection (a) shall apply with respect to appointments to the office of Director of the National Institutes of Health made after the date of the enactment of this Act.*

*Sec. 113. Section 601 of the Medical Facilities Construction and Modernization Amendments of 1970 is amended by striking out "ending prior to July 1, 1974,".*

## *TITLE II—BIOMEDICAL RESEARCH*

*Sec. 201. (a)(1) There is established the President's Biomedical Research Panel (hereinafter in this section referred to as the "Panel") which shall be composed of (A) the Chairman of the President's Cancer Panel (established under section 407(c) of the Public Health Service Act); and (B) six members appointed by the President who by virtue of their training, experience, and background are exceptionally qualified to carry out the duties of the Panel. At least five of the members of the Panel shall be distinguished scientists or physicians. The appointed members of the Panel shall be appointed for the life of the Panel.*

*(2) The President shall designate one of the appointed members to serve as Chairman of the Panel.*

*(3) Appointed members of the Panel shall each be entitled to receive the daily equivalent of the annual rate of basic pay in effect for grade GS–18 of the General Schedule for each day (including traveltime) during which they are engaged in the actual performance of duties vested in the Panel; and while away from their homes or regular places of business in the performance of services for the Panel, all members of the Panel shall be allowed travel expenses, including per diem in lieu of subsistence, in the same manner as persons employed intermittently in the Government service are allowed expenses under section 5703(b) of title 5 of the United States Code.*

*(4) The Panel may appoint and fix the pay of such personnel as it deems necessary to carry out its duties.*

*(b) The Panel shall—*

*(1) review and assess,*

*(2) identify and make recommendations with respect to policy issues concerning the subject and content of, and*

*(3) identify and make recommendations with respect to policy issues concerning the organization and operation of,*

*biomedical and behavioral research conducted and supported under programs of the National Institutes of Health and the National Institute of Mental Health.*

*(c)(1) Not later than the expiration of the 15-month period beginning on the first day of the first month that follows the date on which all of the appointed members of the Panel have taken office, the Panel shall submit simultaneously to the President and to the Congress a comprehensive report of (A) its findings made on the basis of the review and assessment conducted under clause (1) of subsection (b), and (B) the policy issues identified under clauses (2) and (3) of such subsection and the Panel's recommendations with respect to such issues.*

*(2) The Panel shall terminate upon the expiration of the 18-month period beginning on the first day of the first month that follows the date on which all of the appointed members of the Panel have taken office.*

And the House agree to the same.

Harley O. Staggers,
Paul G. Rogers,
David E. Satterfield,
Peter Kyros,
Richardson Preyer,
James W. Symington,
William R. Roy,
Samuel L. Devine,
Ancher Nelsen,
Tim Lee Carter,
J. F. Hastings,
H. John Heinz III,
William H. Hudnut,
*Managers on the Part of the House.*

Edward M. Kennedy,
Harrison Williams,
Gaylord Nelson,
Thomas F. Eagleton,
Alan Cranston,
Harold E. Hughes,
Claiborne Pell,
Walter F. Mondale,
Bill Hathaway,
Richard S. Schweiker,
J. Javits,
Peter H. Dominick,
J. Glenn Beall, Jr.,
Bob Taft, Jr.,
Robert T. Stafford,
*Managers on the Part of the Senate.*

# JOINT EXPLANATORY STATEMENT OF THE COMMITTEE OF CONFERENCE

The managers on the part of the House and the Senate at the conference on the disagreeing votes of the two Houses on the amendment of the House to the bill (S. 2893) to amend the Public Health Service Act to improve the national cancer program and to authorize appropriations for such program for the next 3 fiscal years, submit the following joint statement to the House and the Senate in explanation of the effect of the action agreed upon by the managers and recommended in the accompanying conference report:

The House amendment struck out all of the Senate bill after the enacting clause and inserted a substitute text.

The Senate recedes from its disagreement to the amendment of the House with an amendment which is a substitute for the Senate bill and the House amendment. The differences between the Senate bill, the House amendment, and the substitute agreed to in conference are noted below, except for clerical corrections, conforming changes made necessary by agreements reached by the conferees, and minor drafting and clarifying changes.

## Information Respecting Nutrition and Cancer

The Senate bill required the national cancer program in collecting, analyzing, and disseminating data to include, where appropriate, nutritional programs for cancer patients.

The House amendment changed the requirement that the cancer program collect, analyze, and disseminate "all data" useful with respect to cancer to a requirement that the program collect, analyze, and disseminate "information" useful with respect to cancer and include information respecting nutrition programs for cancer patients and the relationship between nutrition and cancer.

The conference substitute adopts the provision in the House amendment.

## Personnel for the National Cancer Program

The Senate bill required the President and the Office of Management and Budget to allocate to the National Cancer Institute all personnel requested by it to carry out the national cancer program.

The House amendment contained no comparable provision.

The conference substitute follows the House amendment. However, the conference committee noted its concern that the national cancer program and particularly, the clinical center of the NIH have been inadequately staffed; its desire that this be corrected in the future; and its expectation that, where the President, the Office of Management and Budget, or the Department of Health, Education, and Welfare do not make available to the cancer program the personnel which it has requested, they will offer justification for such a failure to provide needed personnel.

### PROGRAMS OF ROUTINE EXFOLIATIVE CYTOLOGY TESTS

The Senate bill contained a requirement that the national cancer control program include programs to provide routine exfoliative cytology tests (Papanicolaou or Pap tests) conducted for the diagnosis of uterine cancer, and authorized for the cancer control program $7 million for this purpose for each of the fiscal years 1975 through 1977.

The House amendment contained no comparable provision.

The conference substitute requires programs to provide appropriate trials of such programs of routine exfoliative cytology tests conducted for the diagnosis of uterine cancer. The conferees intend that of the sums authorized to be appropriated for each fiscal year for cancer control programs $3.5 million is to be considered as authorized to be appropriated for each fiscal year for trials of such programs.

Since controversy exists as to how routine exfoliative cytology tests in mass screening programs can be made effective, efficient, and cost-beneficial, the conference committee felt that it would be appropriate to require appropriate trials of such programs before finally authorizing additional amounts of Federal money for them. There is genuine uncertainty as to the frequency with which such tests should be conducted, which parts of the female population should be included in screening programs utilizing such tests, the settings in which the programs will be most effective, and the nature of follow-up of each positive or possibly positive smear which should be required. It is these questions which the conference committee is hopeful will be answered by large scale trials of the relative merits of various types of screening programs.

### INFORMATION PROGRAMS OF THE NATIONAL CANCER INSTITUTE

The Senate bill contained a requirement that the Director of the NCI conduct or contract for programs to disseminate and interpret on a current basis, for practitioners and other health professionals, scientists and the general public, scientific and other information respecting the cause, prevention, diagnosis and treatment of the disease or other health problems to which the activities of the institute are directed. The director of the NCI was required to issue such regulations as proved necessary to carry out the requirement.

The House amendment contained a similar provision except that it was permissive rather than a requirement, applied only to new information rather than existing, did not require the director of the NCI to issue regulations, and did require the director to include in his annual report a report on the progress, activities and accomplishments of, and expenditures for the information services.

The conference substitute follows the House provision except that it is made a requirement rather than a permissive provision and to apply to both new and existing information.

### PEER REVIEW OF GRANT APPLICATIONS AND CONTRACT PROJECTS

The Senate bill contained a requirement that the director of the NCI provide for proper scientific peer review of research contracts using, to the extent possible, appropriate peer review groups established within the NIH and composed principally of non-federal scientists and other experts in the scientific and disease fields.

The House amendment contained a similar provision except that it applied to grants as well as contracts and to all Institutes of the NIH, the National Institute of Mental Health, the National Institute on Alcohol Abuse and Alcoholism, and the National Institute on Drug Abuse.

The conference substitute follows the House provision.

### SENATE ADVICE AND CONSENT ON APPOINTMENT OF THE DIRECTOR OF THE NIH

The Senate bill contained a requirement that the Senate advise and consent to the appointment of the Director of the NIH.

The House amendment contained no comparable provision.

The conference substitute follows the Senate bill with the addition of language making it clear that the requirement applies only to appointments occurring after the date of enactment of the Act.

### AVAILABILITY OF APPROPRIATIONS

The Senate bill contained a provision stating that notwithstanding any other provision of law, unless enacted after the date of enactment of the provision expressly in limitation of its requirements, funds appropriated for any fiscal year to carry out any program for which appropriations are authorized by the Public Health Service Act or the Mental Retardation Facilities and Community Mental Health Centers Construction Act were to remain available for obligation and expenditure until the end of such fiscal year.

The House amendment contained no comparable provision.

The conference substitute achieves the Senate policy by deleting from section 601 of the Medical Facilities Construction and Modernization Amendments of 1970 the expiration date, thereby making it a permanent provision of law.

### PRESIDENT'S BIOMEDICAL RESEARCH PANEL

The Senate bill contained a requirement that there be established a President's Biomedical Research Panel with the following provisions:

(1) Composition—Five men including the Chairman of the President's Cancer Panel, four members appointed by the President, and at least three members who were distinguished scientists or physicians. The members were to be appointed with staggered terms and one of the appointed members was to serve as Chairman of the panel for a year at a time.

(2) Pay—Members of the panel were to be paid the daily equivalent of the rate for grade GS–18, and appropriate travel expenses.

(3) Meetings—The panel was to meet at the call of the chairman not less often than 12 times a year, with a transcript kept of the proceedings of each meeting and available to the public.

(4) Responsibilities and reports—The panel was to monitor the development and execution of the biomedical and behavioral research programs of the NIH and related institutes, report immediately on any delays or blockages in rapid execution of the programs, submit periodic progress reports and an annual evaluation of the programs' efficacy with suggestions for improvements to the President, and, at the request of the President, submit for his consideration names for consideration for appointment as Director of the NIH.

(5) Term—The panel was to continue in office permanently.

The House amendment contained no comparable provision.

The conference substitute requires the establishment of a President's Biomedical Research Panel with the following provisions:

(1) Composition—Similar to the Senate bill except that members will serve for the life of the Panel and one member, designated by the President, will serve throughout its life as its Chairman.

(2) Pay—Same as the Senate bill.

(3) Meetings—At the discretion of the Panel.

(4) Responsibilities—The Panel is to:

(*a*) review and assess,

(*b*) identify and make recommendations with respect to policy issues concerning the subject and content of, and

(c) identify and make recommendations with respect to policy issues concerning the organization and operation of,

biomedical and behavioral research conducted and supported under the programs of the National Institutes of Health, the National Institute of Mental Health, the National Institute of Alcohol Abuse and Alcoholism, and the National Institute of Drug Abuse.

(5) Report—Not later than 15 months after the appointment of the Panel, it is to submit a report to the President and the Congress of its findings made on the basis of its review and assessment of the biomedical research programs, the policy issues which it has identified, and its recommendations with respect to these issues.

(6) Term—The Panel is to terminate 18 months after the appointment of its members.

Harley O. Staggers,
Paul G. Rogers,
David E. Satterfield,
Peter Kyros,
Richardson Preyer,
James W. Symington,
William R. Roy,
Samuel L. Devine,
Ancher Nelsen,
Tim Lee Carter,
J. F. Hastings,
H. John Heinz III,
William H. Hudnut,

*Managers on the Part of the House.*

EDWARD M. KENNEDY,
HARRISON WILLIAMS,
GAYLORD NELSON,
THOMAS F. EAGLETON,
ALAN CRANSTON,
HAROLD E. HUGHES,
CLAIBORNE PELL,
WALTER F. MONDALE,
BILL HATHAWAY,
RICHARD S. SCHWEIKER,
J. JAVITS,
PETER H. DOMINICK,
J. GLENN BEALL, Jr.,
BOB TAFT, Jr.,
ROBERT T. STAFFORD,

*Managers on the Part of the Senate.*

Public Law 93-352
93rd Congress, S. 2893
July 23, 1974

# An Act

**To amend the Public Health Service Act to improve the national cancer program and to authorize appropriations for such program for the next three fiscal years.**

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,*

National cancer program, improvement.

## TITLE I—EXTENSION OF CANCER PROGRAM

National Cancer Act Amendments of 1974.
42 USC 282 note.

Sec. 101. This title may be cited as the "National Cancer Act Amendments of 1974".

85 Stat. 784.
42 USC 282.

Sec. 102. Section 402(b) of the Public Health Service Act is amended—

(1) by striking out "in amounts not to exceed $35,000" in paragraph (1) and inserting in lieu thereof "if the direct costs of such research and training do not exceed $35,000, but only"; and

(2) by striking out "in amounts exceeding $35,000" in paragraph (2) and inserting in lieu thereof "if the direct costs of such research and training exceed $35,000, but only".

88 STAT. 358
88 STAT. 359

42 USC 286a.

Sec. 103. Section 407(b)(4) of the Public Health Service Act is amended by striking out "all data" and inserting in lieu thereof "information (including information respecting nutrition programs for cancer patients and the relationship between nutrition and cancer)".

Sec. 104. Section 407(b)(7) of the Public Health Service Act is amended by striking out "where appropriate".

Sec. 105. Section 407(b)(9)(A) of the Public Health Service Act is amended by inserting "(including an estimate of the number and type of personnel needed for the National Cancer Program)" after "budget estimate".

42 USC 286b.

Sec. 106. Section 408(a) of the Public Health Service Act is amended by striking out "fifteen".

42 USC 286c.

Sec. 107. (a) Subsection (a) of section 409 of the Public Health Service Act is amended by inserting before the period at the end thereof a comma and the following: "including programs to provide appropriate trials of programs of routine exfoliative cytology tests conducted for the diagnosis of uterine cancer".

(b) Subsection (b) of such section is amended by striking out "and" before "$40,000,000" and by inserting before the period at the end thereof a comma and the following: "$53,500,000 for the fiscal year ending June 30, 1975, $68,500,000 for the fiscal year ending June 30, 1976, and $88,500,000 for the fiscal year ending June 30, 1977".

42 USC 286d.

Sec. 108. Section 410 of the Public Health Service Act is amended—

(1) by striking out "fifty" in paragraph (1) and inserting in lieu thereof "one hundred";

(2) by striking out "and" at the end of paragraph (7);

(3) by striking out the period at the end of paragraph (8) and inserting in lieu thereof "; and";

(4) by adding after paragraph (8) the following new paragraph:

"(9) to award grants for new construction as well as alterations and renovations for improvement of basic research laboratory facilities, including those related to biohazard control, as deemed necessary for the National Cancer Program."; and

(5) by inserting "(a)" after "410." and by adding after paragraph (9) the following new subsection:

Information dissemination program.

"(b)(1) The Director of the National Cancer Institute shall provide and contract for a program to disseminate and interpret, on a current basis, for practitioners and other health professionals, scientists, and the general public scientific and other information respecting the cause, prevention, diagnosis, and treatment of cancer.

85 Stat. 782.
42 USC 286e.

"(2) The Director of the National Cancer Institute shall include in the annual report required by section 410A(b) a report on the progress, activities, and accomplishments of, and expenditures for, the information services of the National Cancer Program."

42 USC 286g.

Sec. 109. Section 410C of the Public Health Service Act is amended by striking out "and" before "$600,000,000" and by inserting before the period at the end thereof a semicolon and the following: "$750,000,000 for the fiscal year ending June 30, 1975; $830,000,000 for the fiscal year ending June 30, 1976; and $985,000,000 for the fiscal year ending June 30, 1977".

88 STAT. 359

88 STAT. 360
Ante, p. 135.

Sec. 110. The part H of the Public Health Service Act relating to the appointment of the Directors of the National Institutes of Health and the National Cancer Institute is redesignated as part I, section 461 of such part is redesignated as section 471, and such part is amended by adding at the end the following new section:

"PEER REVIEW OF GRANT APPLICATIONS AND CONTRACT PROJECTS

42 USC 289l-4.

"Sec. 472. (a) The Secretary, after consultation with the Director of the National Institutes of Health, and, where appropriate, the Directors of the National Institute of Mental Health, the National Institute on Alcohol Abuse and Alcoholism, and the National Institute on Drug Abuse, shall by regulation require appropriate scientific peer review of—

"(1) applications made after the effective date of such regulations for grants under this Act for biomedical and behavioral research; and

"(2) biomedical and behavioral research and development contract projects to be administered after such effective date through an institute established under this title, the National Institute on Alcohol Abuse and Alcoholism, or the National Institute on Drug Abuse.

"(b) Regulations promulgated under subsection (a) shall, to the extent practical, require that the review of grant applications required by the regulations be conducted—

"(1) in a manner consistent with the system for scientific peer review applicable on the date of the enactment of this section to applications for grants under this Act for biomedical and behavioral research, and

"(2) by peer review groups performing such review on or before such date.

"(c) The members of any peer review group established under such regulations shall be individuals who by virtue of their training or experience are eminently qualified to perform the review functions of the group and not more than one-fourth of the members of any peer review group established under such regulations shall be officers or employees of the United States."

79 Stat. 448;
84 Stat. 1308.
42 USC 241.

Sec. 111. Section 301(h) of the Public Health Service Act is amended by striking out "during the fiscal year ending June 30, 1966, and each of the eight succeeding fiscal years".

Sec. 112. (a) The first sentence of section 471 of the Public Health Service Act (as so redesignated by section 110) is amended to read as follows: "The Director of the National Institutes of Health shall be appointed by the President by and with the advice and consent of the Senate; and the Director of the National Cancer Institute shall be appointed by the President."

(b) The amendment made by subsection (a) shall apply with respect to appointments to the office of Director of the National Institutes of Health made after the date of the enactment of this Act.

Effective date.
42 USC 289l note.

Sec. 113. Section 601 of the Medical Facilities Construction and Modernization Amendments of 1970 is amended by striking out "ending prior to July 1, 1974,".

84 Stat. 353;
87 Stat. 95.
42 USC 201 note.

88 STAT. 360

88 STAT. 361

## TITLE II—BIOMEDICAL RESEARCH

Sec. 201. (a)(1) There is established the President's Biomedical Research Panel (hereinafter in this section referred to as the "Panel") which shall be composed of (A) the Chairman of the President's Cancer Panel (established under section 407(c) of the Public Health Service Act); and (B) six members appointed by the President who by virtue of their training, experience, and background are exceptionally qualified to carry out the duties of the Panel. At least five of the members of the Panel shall be distinguished scientists or physicians. The appointed members of the Panel shall be appointed for the life of the Panel.

President's Biomedical Research Panel.
Establishment.
42 USC 289l-1 note.
85 Stat. 779.
42 USC 286a.

(2) The President shall designate one of the appointed members to serve as Chairman of the Panel.

(3) Appointed members of the Panel shall each be entitled to receive the daily equivalent of the annual rate of basic pay in effect for grade GS–18 of the General Schedule for each day (including traveltime) during which they are engaged in the actual performance of duties vested in the Panel; and while away from their homes or regular places of business in the performance of services for the Panel, all members of the Panel shall be allowed travel expenses, including per diem in lieu of subsistence, in the same manner as persons employed intermittently in the Government service are allowed expenses under section 5703(b) of title 5 of the United States Code.

Compensation.
5 USC 5332 note.
80 Stat. 499.

(4) The Panel may appoint and fix the pay of such personnel as it deems necessary to carry out its duties.

(b) The Panel shall—

(1) review and assess,

(2) identify and make recommendations with respect to policy issues concerning the subject and content of, and

(3) identify and make recommendations with respect to policy issues concerning the organization and operation of,

biomedical and behavioral research conducted and supported under programs of the National Institutes of Health and the National Institute of Mental Health.

Duties.

(c)(1) Not later than the expiration of the 15-month period beginning on the first day of the first month that follows the date on which all of the appointed members of the Panel have taken office, the Panel shall submit simultaneously to the President and to the Congress a comprehensive report of (A) its findings made on the basis of the review and assessment conducted under clause (1) of subsection (b), and (B) the policy issues identified under clauses (2) and (3) of such subsection and the Panel's recommendations with respect to such issues.

Report to President and Congress.

Termination. (2) The Panel shall terminate upon the expiration of the 18-month period beginning on the first day of the first month that follows the date on which all of the appointed members of the Panel have taken office.

Approved July 23, 1974.

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LEGISLATIVE HISTORY:

HOUSE REPORTS: No. 93-954 accompanying H.R. 13053 (Comm. on Interstate and Foreign Commerce) and No. 93-1164 (Comm. of Conference).
SENATE REPORT No 93-736 (Comm. on Labor and Public Welfare).
CONGRESSIONAL RECORD, Vol. 120 (1974):
Mar. 26, considered and passed Senate.
May 1, 2, considered and passed House, amended, in lieu of H.R. 13053.
July 9, House agreed to conference report.
July 10, Senate agreed to conference report.

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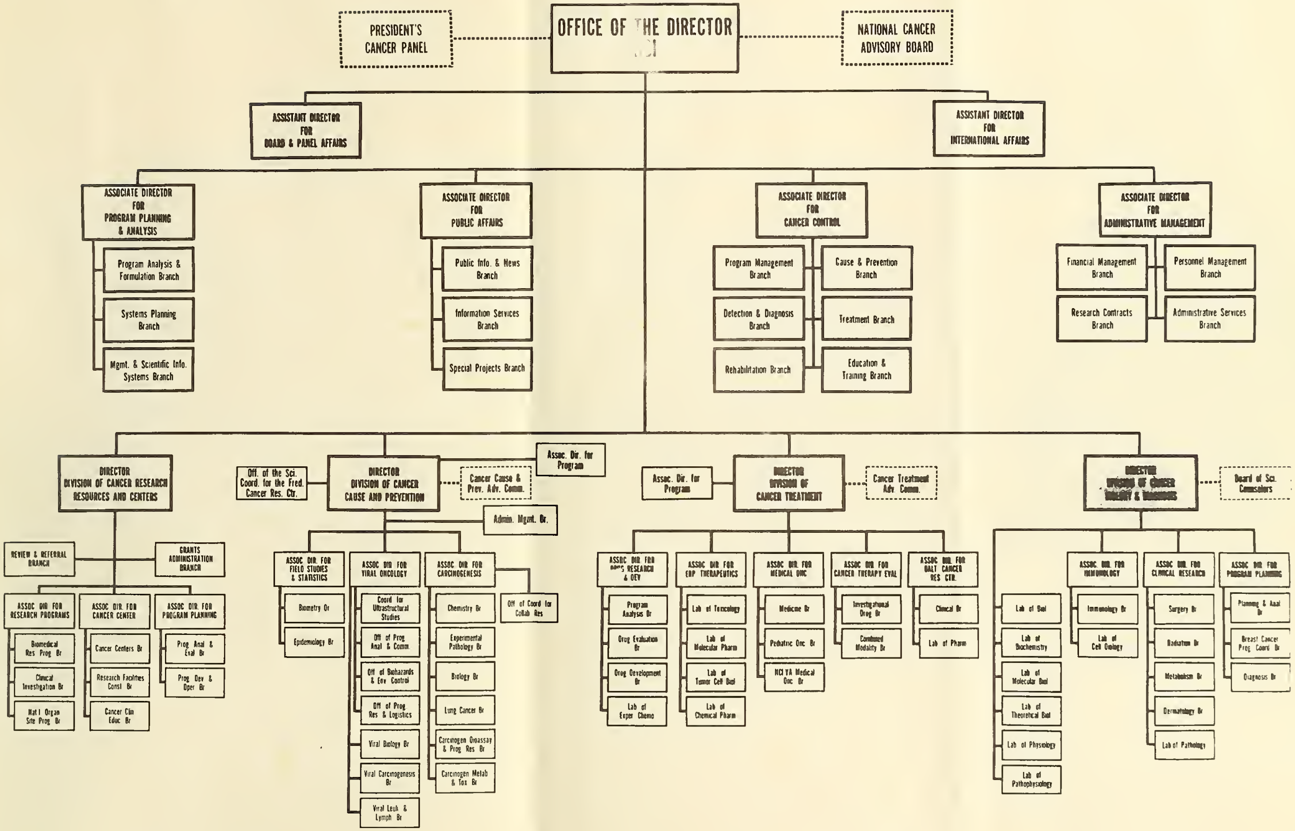
CHART 1.—Organization of the National Cancer Institute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